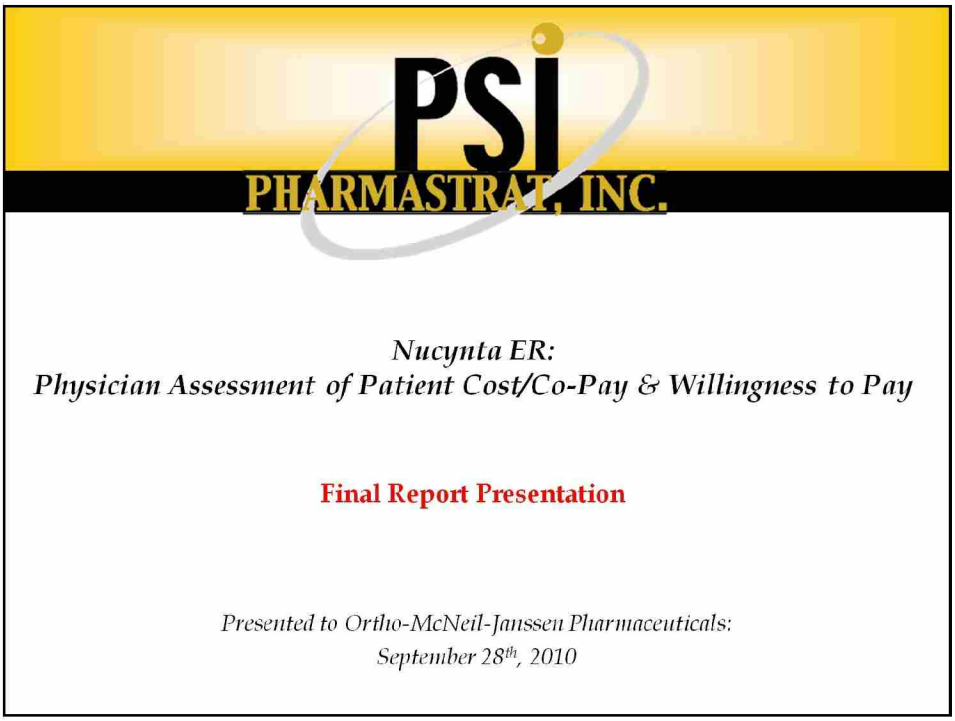
PSJ14 Janssen Opp Exh 32 – JAN00015164

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Project Overview

Research Objectives

The primary objectives of this study are to understand physician perceptions re: patient affordability and how it could influence prescribing behavior for tapentadol extended release helping to inform OMJPI contracting and marketing strategies for the product.

Specific Research Questions Include:

- Understand existing knowledge and perceptions of Nucynta among targeted physicians
  - Perceived appropriate co-pay
  - Awareness of patient affordability programs
- Understand physicians' access and affordability expectations for **newly launched** CII long-acting opioids (LAOs)
  - Determine how access/affordability expectations are formed and how they change over time
  - Identify patient affordability programs for CII LAOs that physicians consider to be most effective
- Obtain perceptions of tapentadol ER product profile and related patient affordability programs
  - Determine physician interest and willingness to prescribe tapentadol ER at various access levels (i.e. Tier 2 vs. Tier 3, open access vs. prior authorization and/or step therapy requirements)
  - Perceived appropriate co-pay for tapentadol ER
  - Anticipated use and preferences for tapentadol ER patient affordability programs
    - ✓ Co-pay card
    - ✓ Voucher
    - ✓ Patient Assistance Programs

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Project Overview

Methodological Approach

- **Method:** 50 qualitative Telephone-Depth Interviews (TDIs) designed to last approximately 45 minutes each. TDIs were web-assisted to allow for exposure to target product profile and patient affordability program stimuli.
- **Timing:** Interviews conducted between August 20th and August 31st, 2010.
- **Sample:** Multi-specialty sample selected from OMJP-provided Nucynta ER physician target list and screening criteria.
  - Primary Care Physicians (PCPs)
  - Pain Specialists
  - Rheumatologists
  - Neurologists
  - Oncologists
- **Research Materials:** Discussion guide designed to blind respondent to research sponsor.
  - Nucynta ER patient affordability program stimuli tested include co-pay card, voucher and patient assistance programs.

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Project Overview

Sample Design & Screening Criteria

- **Physician Screening Criteria:**
  - Physician from OMJP-provided Nucynta ER physician target list
  - Board certified/board eligible in specialty
  - In practice for 2-30 years
  - Does not practice in ME, MA, DC, VT
  - Treat ≥ 70% adult patients
  - Treat ≥ 30 patients with moderate-severe pain
  - Comfortable discussing patient affordability and prescribing considerations related to LAOs
  - Mix of Nucynta prescribers (n=33) and non-prescribers (n=17)
- Screener used to collect following data (provided in appendix):
  - % practice dedicated to pain management
  - # patients treated with opioids per month
  - % opioid Rxs compromised of LAOs
  - # Rxs written for Embeda, Opana ER and Nucynta in past 3 months
  - # times physician detailed on Embeda, Opana ER and Nucynta in past year

Sample Design	
Target Respondent	**Sample Size**
Primary Care Physicians	20
Pain Specialists *(10 Physical Medicine & Rehabilitation Pain Specialists & 5 Anesthesiology Pain Specialists)*	15
Rheumatologists	5
Neurologists	5
Oncologists	5
Total	**50**

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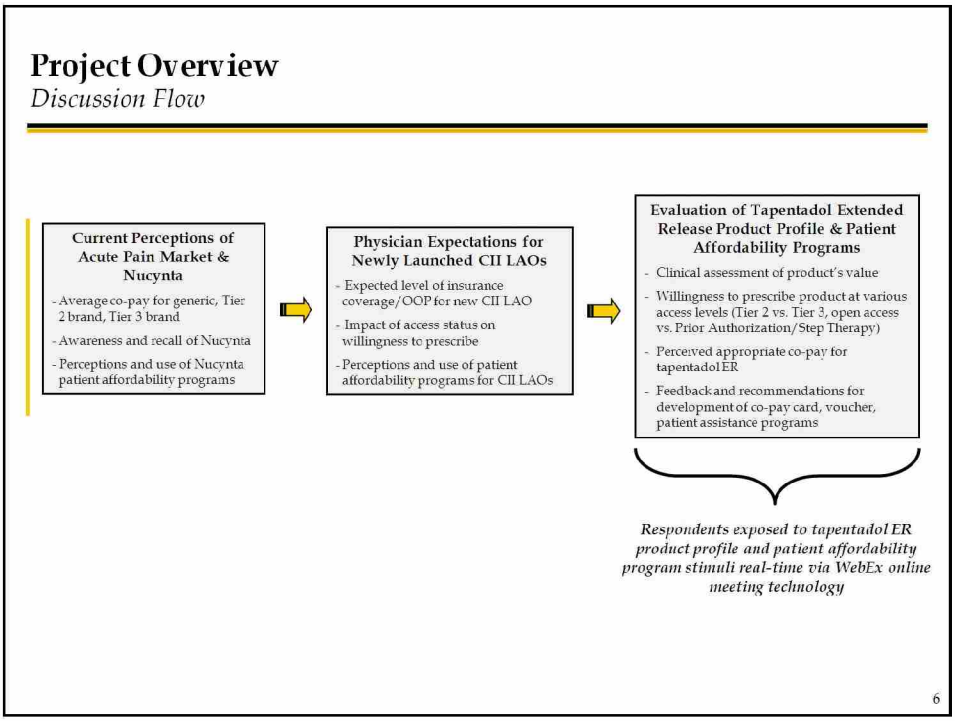

Current Perceptions of Acute Pain Market & Nucynta

Current Perceptions of Acute Pain Market & Nucynta

Role of Patient OOP Cost in Prescribing Choice for CII SAOs

- Physicians perceive that patient affordability has become an increasingly significant focus and concern in recent months with influence on prescribing across all drug categories, including CII short-acting opioids (SAOs).

  "Our goal is to prescribe whatever drug is best for the patient, but cost is becoming a bigger problem this year than last. More and more patients have fixed, limited incomes so sometimes we're left no choice but to prescribe whatever they can afford." ~ PM&R Pain Specialist

- Most report relatively high level of clinical comfort and familiarity with available generic CII SAOs, thus prefer to utilize generic options where possible to avoid potential cost issues.

- When determining whether to prescribe a branded CII SAO rather than a generic, physicians commonly report that the following factors are taken into consideration:
  - Extent to which patient has drug coverage versus is uninsured
  - Extent to which patient has Commercial insurance vs. Medicare Part D or Medicaid coverage (less relative OOP cost concerns reported for Commercial insurance patients)
  - Patient socioeconomic status (threshold at which patient no longer be comfortable paying)

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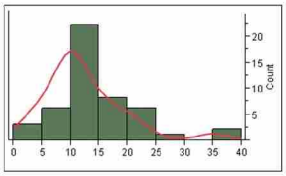
Current Perceptions of Acute Pain Market & Nucynta

Perceived Average Co-Pay Amounts for CII SAOs (Commercial Insurance Plans)

Key Takeaways:

- Physicians report that CII SAOs most commonly have co-pays up to **$10 for generics**, **$25-40 for Tier 2 brands** and **$50-60 for Tier 3 brands** among Commercial insurance plans.
- Reported estimates are fairly consistent with national Commercial benefit design co-pay data[1].

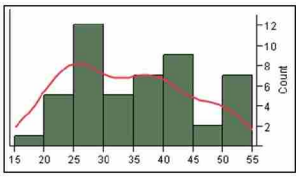
Physician-Reported Co-Pay Amount for Generic CII SAO (# Mentions) (n=50 Physicians)



Reported Co-Pay Amount

Mean	$12
Median	$10

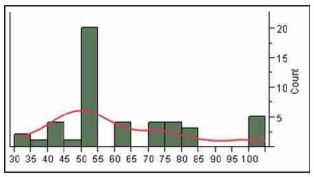
Physician-Reported Co-Pay Amount for Tier 2 Branded CII SAO (# Mentions) (n=50 Physicians)



Reported Co-Pay Amount

Mean	$34
Median	$35

Physician-Reported Co-Pay Amount for Tier 3 Branded CII SAO (# Mentions) (n=50 Physicians)



Reported Co-Pay Amount

Mean	$60
Median	$50

Q: Considering CII SAOs such as Percocet and Opana IR, what do you believe to be the average Commercial health insurance co-pay for a generic prescription, preferred brand prescription (tier 2), and non-preferred brand prescription (tier 3)?

[1] *Kaiser Family Foundation's 2009 Kaiser/HRET Employer Health Benefit Survey reports national average co-pays of $10 (generic), $27 (Tier 2) and $46 (Tier 3).*

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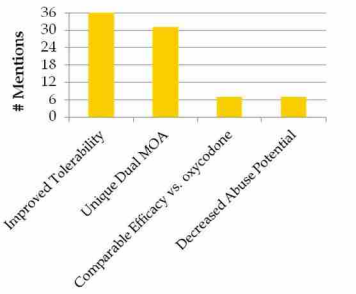
Current Perceptions of Acute Pain Market & Nucynta

Physician Awareness and Recall of Nucynta

- Among physicians sampled in research:
  - 84% recall meeting Nucynta rep at least once in past year
  - 56% report having ≥ 5 Nucynta interactions in past year
- Most report a relatively favorable perception of Nucynta as a result of being informed of key attributes including:
  - Improved tolerability profile vs. SAO alternatives
  - Unique dual MOA
  - Comparable efficacy to oxycodone
  - Decreased abuse potential
- 76% also recall viewing Nucynta advertisements and often remember seeing a lion with a rose in its mouth in journals.

  "The ad has a lion holding a rose in its mouth to signify that Nucynta helps 'tame the beast' which is pain." ~ PM&R Pain Specialist

Nucynta Product Attributes Most Often Recalled from Interaction with Nucynta Rep (# Mentions) (n=42 Physicians Reporting)*



Q: What, if anything do you recall about Nucynta from advertisements or presentations?
**Note: 8 respondents who reported never interacting with rep were not asked this question.*

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Current Perceptions of Acute Pain Market & Nucynta

Access and Affordability Considerations for Nucynta

- While physicians report a relatively favorable perception of Nucynta based on its clinical attributes, they vary in willingness to prescribe Nucynta due to perceived managed care access level and patient out-of-pocket cost.

Physician Type #1: "Had Bad Experiences with Nucynta" (*Less Common*)	**Physician Type #2: "Hesitant to Prescribe Branded CII SAO" (*Most Common*)**	**Physician Type #3: "Primary Focus on Clinical Merits vs. Access/Affordability" (*Less Common*)**
• Encountered PA and/or step therapy requirements (n=4) • Not covered for Medicare Part D/Medicaid patient (n=3) • Co-pay card ran out and patient forced to switch therapy (n=2) • Issue with pharmacy stocking (n=1)	• High comfort level and familiarity with available generic CII SAOs • Anticipate insurance plans will require prior trial of generic(s) • Anticipate patient will be unwilling/unable to pay for brand • "Wait and see" approach or reserve for use after trial of multiple generics	• Perceive patient population has little difficulty affording Nucynta • Have yet to receive patient complaints or calls from pharmacy reporting barriers to use • Willing to prescribe Nucynta even if access is restricted/patient expresses cost concern given it's clinical merits
Least Likely to Prescribe Nucynta	*Willing to Prescribe Nucynta Depending on Individual Patient*	*Primary Focus on Ensuring Patient Prescribed Most Clinically Appropriate Product*

Willingness to Prescribe Nucynta

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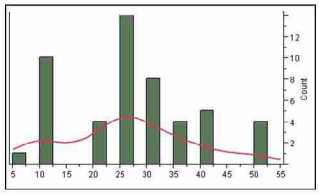
Current Perceptions of Acute Pain Market & Nucynta

Perceived Appropriate Co-Pay Amount for Nucynta

Key Takeaways:
- Physicians most commonly believe that **up to $25-30 is an appropriate co-pay for Nucynta** given availability of generic CII SAOs.
- Physicians most commonly believe that majority of their patients can **afford up to $25-30** per month.

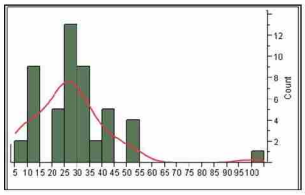
Co-Pay Amount Reported As Appropriate for Nucynta by Physicians (# Mentions)
(n=50 Physicians)*



Reported Co-Pay Amount

Mean	$26
Median	$25

Co-Pay Amount for Nucynta that Physicians Believe Majority of Patients Can Afford (# Mentions)
(n=50 Physicians)*



Reported Co-Pay Amount

Mean	$27
Median	$25

Q1: What co-pay amount do you feel is appropriate for Nucynta given your clinical experience with the product?
Q2: What co-pay amount do you think the majority of your patients can afford?
**Note: Among 8 respondents who reported no awareness of Nucynta, respondents were asked to provide an appropriate co-pay amount for any branded CII SAO.*

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Current Perceptions of Acute Pain Market & Nucynta

Awareness & Satisfaction with Nucynta Patient Affordability Programs

	Nucynta Co-Pay Card	Nucynta Voucher
Program Description	• Pay no more than $25 per Rx[1] • Up to 3 times per 12 months[1]	• Voucher for free supply of 10 pills[2]
Awareness of Program	• 64% (n=32) report awareness of card • 28% able to recall $25 OOP cost or ability to use up to 3 times per year	• Only 30% (n=15) mention awareness of voucher
Reported Use of Program	• All but 3 who are aware of program use card • Only for patients with Commercial insurance	• All but 1 who are aware of program use voucher • Expanded use outside of patients with Commercial insurance
Favorable Elements of Program	• Like simplicity of *"Pay No More Than $25"* • Aligns with OOP amount that physicians feel is appropriate and majority of patients can afford	• Some see voucher as useful alternative to samples
Concerns with Program	• A few report running into affordability issues with patients who exhaust use of the card	• Others perceive that all vouchers are a hassle given need to write 2 Rxs • A few hesitant to provide free pills for CII products

[1]: *Source – MOSAIC Co-Pay Assistance Audit, August 13 2010*
[2] *Source – Physician-reported information provided during course of TDIs*

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Project Overview

Research Findings

- *Current Perceptions of Acute Pain Market & Nucynta*
- **Access & Affordability Expectations for New CII LAOs**
- *Tapentadol ER Profile Evaluation and Willlingness to Prescribe*
- *Feedback on Tapentadol ER Patient Affordability Programs*

Appendix

Access & Affordability Expectations for New CII LAOs

Access & Affordability Expectations for New CII LAOs

Expected Level of Insurance Coverage for Newly Launched CII LAOs

- Physicians sampled typically expect that any newly launched CII LAO will be associated with relatively poor managed care access upon entering the market:
  - Most likely non-preferred brand on Tier 3
  - Subset believe that insurance plans will not cover drug early on
  - Minimum of 6 months to over 1 year post-launch reportedly required before changes made
- Expected managed care access for newly launched CII LAOs is often based on prescribing experiences with existing products. Some perceive that challenges encountered with newer CII LAOs may be indicators of how insurance companies will handle future entrants:

Reported Example	Physician Experience Prescribing Product Upon Entrance Into Market
Embeda	• Perceive that insurance plans hesitant to approve use or offer at comparable access level to OxyContin CR despite tamper resistant properties
Exalgo	• Among minority who report awareness of Exalgo, a small subset indicate that patients required to pay entire cost out of pocket • Issues with retail pharmacy stocking also reported even if drug is covered

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Access & Affordability Expectations for New CII LAOs

Determination of Insurance Coverage for Newly Launched CII LAOs

Means of Determining Insurance Coverage for New CII LAO	Reported Frequency of Using Approach	Commonly Reported Physician Considerations
Provided Info by Rep	Highest Frequency	• Minimal desire/time to proactively search for coverage information • Rely of rep to supply info. for major health plans in area • While initially helpful, info. can become outdated quickly
Informed by Pharmacist or Patient Once Rx Already Written	Moderate Frequency	• Learn by "trial and error" once patient takes Rx to pharmacy • Too difficult to keep track of info. provided by rep or report gaps in rep info. given complexities of benefit design
Provided Info by MCO	Lower Frequency	• Small subset perceive they have ample office staff to call health plan directly (i.e. Rheum or Onc practices with dedicated support staff)
Utilize EMR Capabilities	Lower Frequency	• Minority report being directed to preferred formulary agents and potential formulary restrictions via EMR
Consult Resources like Epocrates and Fingertip Formulary	Lower Frequency	• 2 physicians prefer to look up insurance coverage on Epocrates or Fingertip formulary before giving Rx to patient

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Access & Affordability Expectations for New CII LAOs

Role of Patient OOP Cost in Prescribing Choice for CII LAOs

- Relative to CII SAOs, most physicians perceive that slightly less cost sensitivity exists for CII LAOs given presence of fewer generics, increased patient willingness to pay for effective chronic pain relief and expectation that patients may switch opioid products.
- Physicians still report receiving relatively frequent patient complaints regarding the cost of CII LAOs. The extent to which complaints diminish future likelihood of prescribing varies:

Physician Type #1: "Take Path of Least Resistance"
(More Commonly PCPs)
- Perceived as strain on physicians' time
- May have limited staff to accommodate patient complaints
- Prefer prescribing alternatives with less hassle

→ *OUTCOME: Limit Subsequent Prescribing Where Possible*

Physician Type #2: "Willing to Look Past Additional Hurdle"
(More Commonly Specialists)
- Evaluate patient on case by case basis rather than rule out drug due to cost
- Often have dedicated staff to assist with patient affordability needs (i.e. Oncs, Rheums due to use of higher cost agents)

→ *OUTCOME: Open to Prescribing Drug for Clinically Appropriate Patients Even if Experience Patient Complaints*

Q: At what point do patient complaints impact your likelihood to prescribe a product across all third-party payer types?

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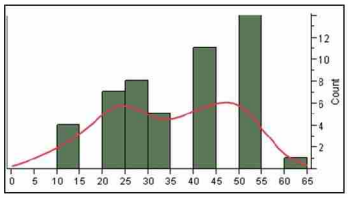
Access & Affordability Expectations for New CII LAOs

Perceived Appropriate Co-Pay Amount for Any Newly Launched CII LAO

Key Takeaways:
- Variability exists in co-pay amounts that physicians perceive are appropriate for any new CII LAO.
- One group report that **up to $25-35** is appropriate, while second group think **up to $40-50** is appropriate.
- Perceive that patients most commonly are **able to pay up to $30-35** given current economic climate and anticipated duration of use.

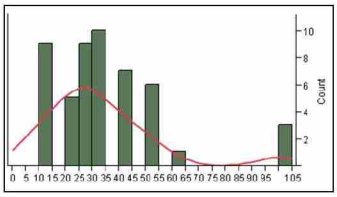
Co-Pay Amount Reported As Appropriate for Any Newly Launched CII LAO by Physicians (# Mentions) (n=50 Physicians)



Reported Co-Pay Amount

Mean	$35
Median	$40

Co-Pay Amount for Any Newly Launched CII LAO that Physicians Believe Majority of Patients Can Afford (# Mentions) (n=50 Physicians)



Reported Co-Pay Amount

Mean	$33
Median	$30

Q1: What co-pay amount do you feel is appropriate for any new CII LAO? Q2: What co-pay amount do you think the majority of your patients can afford?

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Access & Affordability Expectations for New CII LAOs

Current Use and Perceptions of Patient Affordability Programs for CII LAOs

	Current Use of CII LAO Patient Affordability Programs
Current Awareness & Use of Programs	• 92% report general awareness of co-pay savings programs among existing CII LAOs • Most cannot recall specific details of individual co-pay savings programs • Recall of programs dependent on frequency of CII LAO prescribing, patient mix (i.e. Commercial vs. Medicare Part D/ Medicaid) and interactions with reps
Preferences for Accessing Programs	• Most prefer that rep provide materials to physician • Open to patients accessing programs via web but little desire for physician/staff to be involved with web resources
Preferences for Programs At Office	• Most often kept in sample closet, or less frequently in exam room or physician's desk • Physicians open to being provided dispenser/holder for cards, however not considered essential – Subset have organized, alphabeticized layout to ensure easy access at office – Handful report that area for cards is currently disorganized and thus not optimal for use
Preferences for Use by Patient At Pharmacy	• Often uncertain how patients use affordability programs at pharmacy • Prefer that patients not be required to activate card or send information via mail

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Access & Affordability Expectations for New CII LAOs

Product-Specific Feedback on Current Patient Affordability Programs

- Physicians report greatest use and most favorable perception of OxyContin CR's co-pay savings program among existing CII LAOs given extent of savings offered per month. Ability to recall details of other products' co-pay savings programs is limited in comparison.

Product	Program Description	Reported Frequency of Use	Common Perceptions of Program
OxyContin CR	• Co-pay card[1] • Save up to $70 per Rx[1] • Up to 12 months[1]	High	• Perceived benchmark for CII LAO programs • Some believe that card can no longer be used
Opana ER	• Instant savings card[2] • Save up to $25 per Rx[2] • Up to 12 months[2]	Moderate	• Relatively neutral opinion reported
Embeda	• Preferred co-pay program[2] • Save up to $60 per Rx[2] • Up to 6 months[2]	Moderate	• Subset of physicians report receiving patient complaints regarding cost despite handing out co-pay program
Kadian	• Coupon[2] • Save up to $50 per Rx[2] • 24 months[2]	Modest	• Minimal recollection of program reported
Avinza	• Coupon[1] • Save up to $30 per Rx[1] • Up to 6 months[1]	Modest	• Minimal recollection of program reported
Exalgo	• Co-pay card[1] • Save up to $40 per Rx[1] • Unaware of duration[1]	Modest	• Minimal recollection of program reported

[1]: *Source – Physician-reported information provided during course of TDIs* [2]: *Source – MOSAIC Co-Pay Assistance Audit, August 13 2010* 20

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Research Findings

- *Current Perceptions of Acute Pain Market & Nucynta*
- *Access & Affordability Expectations for New CII LAOs*
- **Tapentadol ER Profile Evaluation & Willingness to Prescribe**
- *Feedback on Tapentadol ER Patient Affordability Programs*

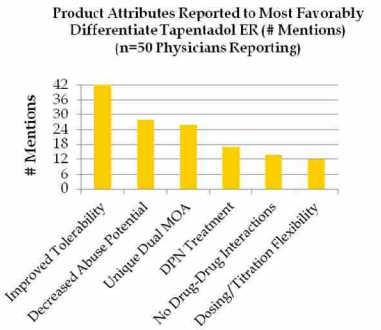
Appendix

Tapentadol ER Profile Evaluation & Willingness to Prescribe

Tapentadol ER Profile Evaluation & Willingness to Prescribe

Clinical Evaluation of Tapentadol ER Product Profile

- Majority report overall favorable perception of tapentadol ER versus existing chronic pain treatments.
  - Competitive reference set: CII LAOs (OxyContin CR, long-acting morphine products and fentanyl patch), followed by neuropathic pain products (Lyrica).
- Differentiating attributes for tapentadol ER are reported to include:
  - Improved tolerability (i.e. lower GI side effects)
  - Decreased abuse potential & tamper-resistant properties
  - Unique dual MOA/norepinephrine reuptake inhibition
  - Potential ability to treat DPN
  - No drug-drug interactions
  - Dosage and titration flexibility
- Areas of question for which physicians request additional information include:
  - Dosing conversion to determine if patients on OxyContin CR could be switched to tapentadol ER based on max dose
  - Clarification on possibility of serotonin syndrome



Note: TPP language re: TRF

Q: What attributes most favorably differentiate tapentadol ER?

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Tapentadol ER Profile Evaluation & Willingness to Prescribe

Anticipated Prescribing of Tapentadol ER

- Based solely on the clinical profile (not taking access and affordability into consideration), most physicians report a relatively high willingness to prescribe tapentadol ER.
- Physicians most often anticipate prescribing tapentadol ER for the following:
  - Patients with demonstrated tolerability issues on one or more CII LAO
  - Patients with uncontrolled neuropathic pain
  - Patients prone to drug abuse
- Qualitatively, the extent to which physicians anticipate becoming early adopters of tapentadol ER versus take a wait and see approach to prescribing is reported to vary:
  - A number of pain specialists with extensive existing knowledge and highly favorable perception of Nucynta report that they have been anticipating approval of tapentadol ER
    "I can't wait for tapentadol ER to hit the market. Nucynta is a great drug and I've been waiting for a long-acting version ever since Nucynta got approved." ~ Anesthesiology Pain Specialist
  - In contrast, PCPs tend to report a preference to stick with familiar agents as opposed to prescribing tapentadol ER in order to assess feedback from early adopters
    "I'm a creature of comfort when it comes to trying new drugs. For a product like this, I'd sit back for a while until I can get a feel for how good the drug really is." ~ PCP

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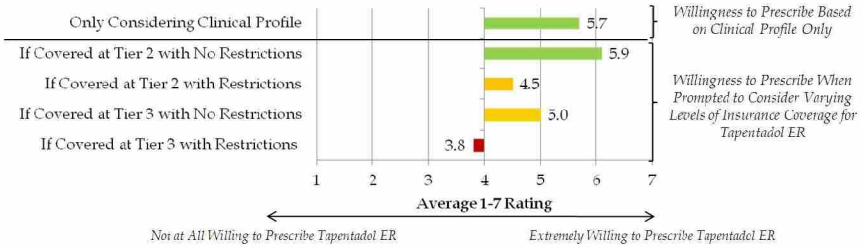
Tapentadol ER Profile Evaluation & Willingness to Prescribe

Impact of Managed Care Access Level on Willingness to Prescribe

Key Takeaway:
- Relative to patient OOP cost, formulary restrictions are often anticipated to represent greater deterrents to prescribing of tapentadol ER
- Prior authorization reported as most likely to deter prescribing, based on perceived burden placed on office staff (i.e. paper submission to insurance plan, time on phone, delay in initiating treatment)

Physician-Reported Willingness to Prescribe Tapentadol ER – Average Rating (1-7 Scale)
(n=50 Physicians Reporting)



Q1: Based on the clinical profile, how would you rate your willingness to prescribe tapentadol ER using a 1-7 scale, where a 1 means "not at all willing to prescribe" and a7 means "extremely willing to prescribe"?
Q2: For each access scenario, I am interested in how you would rate your willingness to prescribe tapentadol ER using a 1-7 scale, where a 1 means "not at all willing to prescribe" and a 7 means "extremely willing to prescribe."
Note: Restrictions defined as Prior Authorization and/or Step Therapy Requirements

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Tapentadol ER Profile Evaluation & Willingness to Prescribe

Affordability Expectations for Tapentadol ER

- Physicians fall in one of two groups with respect to the co-pay amount they perceive is appropriate for tapentadol ER:
  - One group reports that up to $25-35 is appropriate (similar to a Tier 2 co-pay)
  - Another group perceives that up to $40-50 is appropriate (similar to a Tier 3 co-pay)
- Most physicians anticipate that a majority of their patients will be able to afford closer to $30-35 per month for tapentadol ER.
- When probed, most report that a co-pay of $25-30 would facilitate 1st line prescribing of tapentadol ER without hesitation due to cost.
  - Believe that $25-30 would be competitive relative to monthly OOP costs for patients who use co-pay savings programs for existing CII LAOs.

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Feedback on Tapentadol ER Patient Affordability Programs

Feedback on Tapentadol ER Patient Affordability Programs

Overall Impact of Tapentadol ER Affordability Programs on Physician Prescribing

- Most physicians report that having access to patient affordability programs for tapentadol ER will play a significant role in their willingness to prescribe the product, particularly for patients with Commercial health insurance.

  "Without these affordability programs, I wouldn't prescribe tapentadol ER. These drugs are just too costly without co-pay cards or coupons and we want to avoid getting calls back from patients saying they can't afford their medication." ~ PCP

  "You breed loyalty among physicians with these affordability programs. I used to prescribe a lot of Kadian because it had a $50 off coupon. They stopped allowing use of the coupon 6 months ago and patients went back to MS Contin." ~ Anesthesiology Pain Specialist

  "Knowing that these types of affordability programs are available absolutely factors into my decision of whether or not to prescribe a new drug like tapentadol ER. If a drug company can help reduce the cost burden to the patient, I'm much more likely to prescribe their product." ~ Oncologist

- In the absence of co-pay savings programs for patients with government-funded insurance, physicians report that patient assistance programs and foundation support serve as the primary affordability program for these patients.
  - The extent to which the enrollment process is perceived to be simple and straightforward for office staff and patients is reported as the main determinant of physician willingness to promote and use patient assistance programs and foundation support for tapentadol ER.

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Feedback on Tapentadol ER Patient Affordability Programs

Tapentadol ER Co-Pay Card: Overall Physician Feedback & Recommendations

	Commonly Reported Feedback on Co-Pay Card
Feedback on "*Pay No More Than $X*"	• Majority prefer "*Pay No More Than*" vs. "*Save up to*" language because eliminates variability in patient OOP cost and easier for physician to remember and explain • $25-30 monthly cost reported as appropriate amount for co-pay card • Believe that most patients can afford $30-35, but amount closer to $25 felt to be more competitive versus $60-70 co-pay savings offered by OxyContin CR and Embeda
Preferences for Duration of Use	• Most recommend use of co-pay card 12 times per year vs. 6 times per year • Anticipate that subset of patients would be willing to pay for drug once card exhausted after 6 months depending on satisfaction with pain relief, however most would be unable/unwilling to pay more than $30-35 without card *"In my experience having a co-pay card that's only good for 6 months is like taking water away from a thirsty man. It's a big tease and then patients are just stuck." ~ PCP* *"Ideally patients would pay no more than $25 for 12 months so you can keep the amount uniform to the short-acting product, but $30-$35 is still workable because there aren't a ton of generics in the market yet." ~ PM&R Pain Specialist*
Additional Physician Recommendations for Co-Pay Card	• Ensure co-pay card does not need to be activated prior to use • Some recommend that card can e-filed at pharmacy for future use • Ensure that pharmacies are willing to accept co-pay card (problems mentioned with Walgreens in particular)

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Feedback on Tapentadol ER Patient Affordability Programs

Tapentadol ER Co-Pay Card: Aided Feedback Regarding 6 Month vs. 12 Month Use

Key Takeaways:
- Prefer that patients be able to use the tapentadol ER co-pay card **12 times per calendar year, even if required to pay a slightly higher co-pay (i.e. $30-35)**, given anticipated duration of use.
- Almost 60% believe that unless patients find significant pain relief on tapentadol ER, they will be unable/unwilling to pay for the medication if their co-pay card runs out after 6 months.

Tapentadol ER Co-Pay Card: Physician Preference for "Pay No More than $25 for 6 Months" vs. "Pay No More than $30-35 for 12 Months"
(N=50 Physicians Reporting)

Q: What are your thoughts on the statement that "Commercial plan patients will pay no more than $25 per month" for 6 months? The co-pay card could also be developed such that patients would pay a higher $ amount per month (i.e. $30-35) but would be able to use the card for 12 months. Which type of co-pay card is more appropriate for tapentadol ER?

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Feedback on Tapentadol ER Patient Affordability Programs

Tapentadol ER Voucher: Unaided Feedback on "Voucher for X Day Supply"

Key Takeaway:
- Among physicians who anticipate using a voucher for tapentadol ER, most desire that **at least a 14 day supply** be offered.
- Would use to assess level of pain relief and ensure patient tolerability prior to prescribing.

Tapentadol ER Voucher: Physician Preference for Free Pill Supply (# Mentions)
(n=50 Physicians Reporting)

Desired # of Days Supply of Tapentadol ER with Voucher

Desired # of Days Supply of Tapentadol ER with Voucher	
Median	14 Day Supply

Q: What type of pill supply would you require or expect for the tapentadol ER voucher?

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Feedback on Tapentadol ER Patient Affordability Programs

Considerations for Booklet with Co-Pay Card & Voucher Included

- Among the subset of physicians who were exposed to a stimuli slide that presented the tapentadol ER voucher and co-pay card in a booklet, most respondents report a favorable perception of the booklet.
  - Often perceive that booklet would simplify and streamline the amount of materials that physicians keep track of.

    "Whatever you can do to make the process as simple as possible increases the likelihood that I'll remember to give this to the patient. I like having a handout that I can explain to the patient all at once, and they might be more willing to use the drug if they know about the co-pay card when I give them the voucher." ~ Anesthesiology Pain Specialist

- A portion of physicians, however, question whether having the co-pay card and the voucher in a booklet would potentially confuse physicians and patients.
  - Some believe that if Medicare Part D, Medicaid or cash-pay patients were accidentally given the booklet with the co-pay card, patients may attempt to use the card even if instructed about eligibility criteria
  - A few would prefer to hand out the co-pay card only once certain that the patient intends to move forward with using tapentadol ER following trial of the voucher

Q: Would you prefer to have both cards (i.e. co-pay card & voucher) in one booklet, even though some patients (i.e. Medicare) cannot take advantage of one of those cards? If that stipulation was made clear, would that be better than having 2+ cards to manage?
**Note: Question added to discussion guide after initiation of TDIs. As such, n=22 respondents were directly asked this question.*

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Feedback on Tapentadol ER Patient Affordability Programs

Tapentadol ER Patient Assistance Programs: Overall Feedback & Recommendations

	Commonly Reported Feedback on Patient Assistance Programs
Overall Perceptions & Anticipated Use	• Generally perceive that programs can be time-consuming and burdensome due to paperwork required to enroll patients and eligibility stipulations • Limited use and recall of PAPs reported for CII LAOs (2 report previous use of Purdue program for OxyContin CR) • Perceive that patients will try a different medication rather than wait to enroll in a PAP • Physicians generally ambivalent whether support is obtained via the manufacturer or Together Rx Access Prescription Savings Program – *"It makes no difference to me what specific program the patient would enroll in. My main concern is that the enrollment be as easy and fast as possible, given that these patients are in need of timely pain relief."* ~ Rheumatologist
Additional Physician Recommendations for PAPs	• Desire that PAP enrollment process be as streamlined as possible given time constraints on staff and severity of patients' pain • Suggest 1 uniform enrollment process across entire product portfolio offered by manufacturer • Suggest having single 1-800# as gateway to all foundation support programs and PAPs

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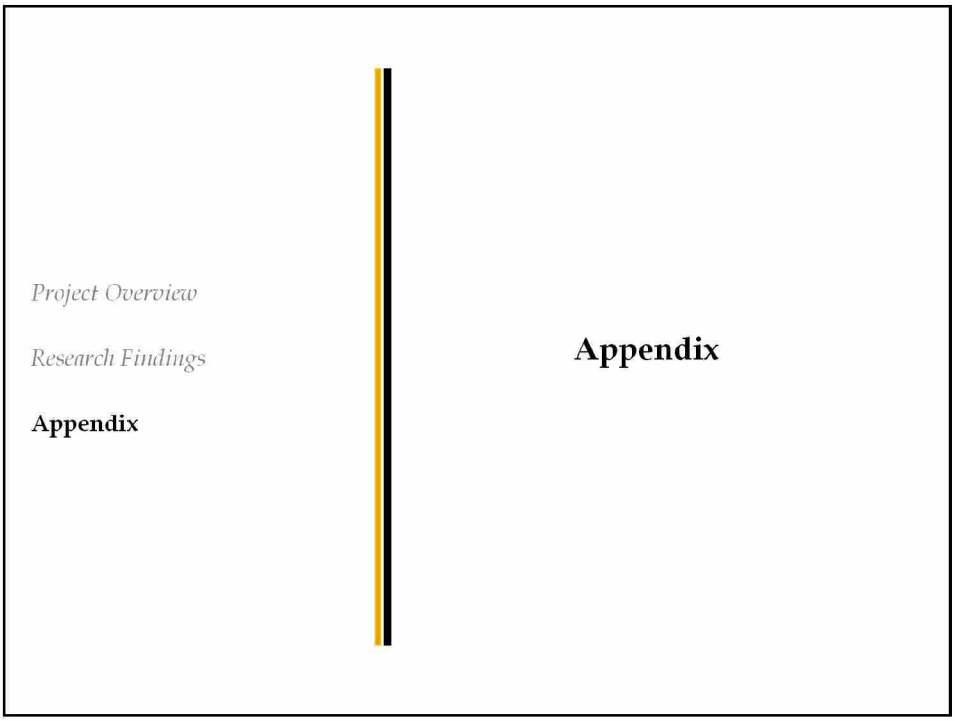
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Executive Summary

Willingness to Prescribe Tapentadol ER

- Managed care access and patient affordability are reported as increasingly influential factors in physicians' prescribing considerations for CII LAOs given current economic climate
- Most anticipate that a new CII LAO like tapentadol ER would be covered as a non-preferred brand or may not be covered for at least 6 months to over 1 year post-launch
- While a majority of physicians report an favorable clinical perception of tapentadol ER based on review of the profile, a number anticipate that potential prior authorization or step therapy requirements would hinder willingness to prescribe the product in the event that physicians' perceive a viable treatment alternative is available without access barriers

Affordability Considerations for Tapentadol ER

- Appropriate co-pay amounts for Tapentadol ER reported by physicians are consistent with co-pay amounts felt to be appropriate for any newly launched CII LAO
- One subset of physicians reports that up to $25-35 is appropriate (similar to Tier 2 co-pay), while a second subset indicates that up to $40-50 (similar to Tier 3 co-pay) is appropriate
- Physicians most commonly perceive that a majority of patients could afford up to $30-35 per month
- Most physicians expect that tapentadol ER would be accompanied by patient affordability programs, particularly a co-pay card, given their availability for existing CII LAOs (i.e. OxyContin CR, Embeda, Opana ER).

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Appendix

Executive Summary

Tapentadol ER Co-Pay Card

- Physicians report a favorable perception of *"Pay No More Than $X"* language relative to co-pay savings programs offered for many existing CII LAOs
- $25-30 most commonly represents the monthly cost that physicians believe the card should offer, based on expectations as to the amount that patients would be able to afford and level of co-pay savings provided by competitor CII LAOs
- Physicians are more likely to prefer having a card that can be used up to 12 times per calendar year as opposed to 6 months per year, even if patients are required to pay a slightly higher co-pay (i.e. $30-35).

Tapentadol ER Voucher

- 75% of physicians express interest in using the voucher under the thinking that patients could utilize a free supply of pills in order to ensure patient tolerability and gauge level of pain relief
- Most prefer that at least a 14 day supply be offered

Tapentadol ER Patient Assistance Programs

- Physicians often associate these programs with extensive enrollment processes that may require significant time from office staff, thus recommend that simplified paperwork and one 1-800# for assistance be offered to increase likelihood of smooth use for office staff as well as patients

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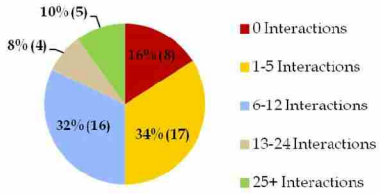
Appendix

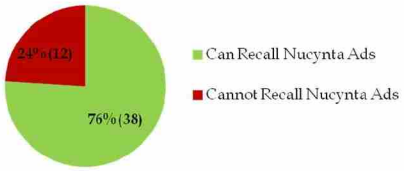
Physician Awareness and Recall of Nucynta

Key Takeaways:
- 50% physicians report meeting with Nucynta rep ≤5 times within past year.
- Other half report more frequent rep interactions ranging from once every 2 months up to once a week.
- Most recall seeing Nucynta advertisements in journals (i.e. picture of "lion with rose").

# of Live Company Interactions for Nucynta Within Past Year Reported by Physicians
(N=50 Physicians Reporting)



Physician-Reported Recall of Nucynta Advertisements Seen Within Past Year
(N=50 Physicians Reporting)



Q: In the past year, can you estimate how many times you have seen advertisements or had live company interactions regarding Nucynta?

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Appendix

Managed Care Access Expectations for Tapentadol ER

- Physician expectations regarding initial insurance coverage for tapentadol ER mirror expectations reported for any newly launched CII LAO.
  - Anticipate initial coverage as non-preferred brand on Tier 3
  - Predict greater potential for access restrictions (PA and/or step therapy requirements) among Medicare Part D plans and Medicaid

- Physician willingness to prescribe tapentadol ER in the event that PA and/or step therapy requirements exist depends on physician specialty, office staff capabilities and restriction language.
  - Most prefer avoiding formulary restrictions where possible
  - Specialists qualitatively report greater willingness to work through requirements if convinced patient is appropriate candidate

    "Prior Authorizations have become an absolute nightmare for us. If I can get the patient on a relatively comparable drug without the hassle, I'm not going to waste time trying to get tapentadol ER approved." ~ PCP

    "I'm a high prescriber of these types of drugs. If I want to prescribe tapentadol ER, I'll find a way to convince the insurance company to give it to the patient." ~ Anesthesiology Pain Specialist

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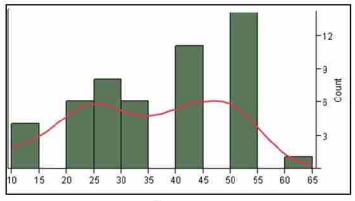
Appendix

Perceived Appropriate Co-Pay Amount for Tapentadol ER

Key Takeaways:

- One group of physicians reports that **up to $25-35 is an appropriate co-pay amount** for tapentadol ER , while a second group indicates that **up to $40-50 is appropriate** for tapentadol ER (similar to amounts provided when asked to consider any newly launched CII LAO).
- Patients are most commonly perceived to be **able to pay up to $30-35** per month.

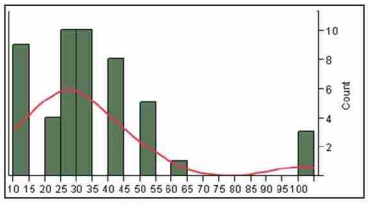
Co-Pay Amount Reported As Appropriate for Tapentadol ER by Physicians (# Mentions)
(n=50 Physicians)



Reported Co-Pay Amount

Mean	$35
Median	$40
Upper 95% Mean	$39
Lower 95% Mean	$31

Co-Pay Amount for Tapentadol ER that Physicians Believe Majority of Patients Can Afford (# Mentions)
(n=50 Physicians)



Reported Co-Pay Amount

Mean	$33
Median	$30
Upper 95% Mean	$39
Lower 95% Mean	$27

Q1: What co-pay amount do you feel is appropriate for tapentadol ER based on review of the product profile?
Q2: What co-pay amount do you think the majority of your patients can afford?

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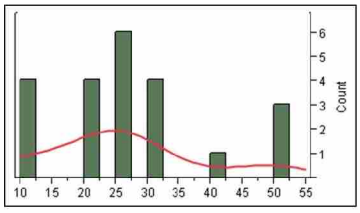
Appendix

Co-Pay Amount Perceived to Facilitate 1st Line Use of Tapentadol ER

Key Takeaway: Physicians most commonly report that $40-50 represents an appropriate co-pay for tapentadol ER; however, when probed to consider a monthly cost that would remove affordability concerns and **drive 1st line use of tapentadol ER**, physicians most commonly cite a co-pay up to **$25-30**.

Physician-Reported Co-Pay Amount for Tapentadol ER that Would Drive 1st Line Use (# Mentions) (n=22 Physicians Reporting)*



Reported Co-Pay Amount

Mean	$26
Median	$25
Upper 95% Mean	$32
Lower 95% Mean	$30

Q1: *What co-pay amount do you feel would drive first line use of tapentadol ER?*
**Note: Question added to discussion guide after initiation of TDIs. As such, n=22 respondents were directly asked this question.*

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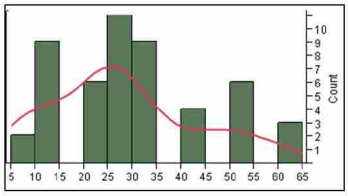
Appendix

Tapentadol ER Co-Pay Card: Unaided Feedback on "Pay No More Than $X"

Key Takeaway: Most physicians believe that patients with Commercial health insurance **should pay no more than $25-30 per month** with the tapentadol ER co-pay card, based on expectations of what majority of their patients can afford and knowledge of current co-pay savings offered by competitor CII LAOs.

Tapentadol ER Co-Pay Card: Co-Pay Amount Desired by Physicians for *"Pay No More than $X"* (# Mentions)
(n=50 Physicians Reporting)



Reported Co-Pay Amount

Mean	$28
Median	$25
Upper 95% Mean	$32
Lower 95% Mean	$24

Q: If tapentadol ER were to have a co-pay card that offered a maximum monthly co-pay that a patient would have to pay, what amount do you think is appropriate?

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Appendix

Tapentadol ER Voucher: Overall Physician Feedback & Recommendations

	Commonly Reported Feedback on Voucher
Overall Perceptions & Anticipated Use	• ***75% of physicians express interest in using the tapentadol ER voucher*** in order to: – Gauge drug's efficacy and patient satisfaction with level of pain relief – Ensure patient tolerability – Determine appropriate dosage form • Of note, most physicians do not believe that they would utilize the voucher to initiate patients on tapentadol ER while awaiting PA approval – Some report that they have used this tactic in the past (Lyrica most commonly mentioned as example), however many express concern that the PA may not be approved • 25% of physicians sampled indicate that they would not use a voucher for tapentadol ER based on their perception that writing 2 prescriptions is burdensome to the physician or violates their practice's policy not to provide any free supplies of narcotics
Preferences for Pill Supply Offered	• Most physicians perceive that ***at least a 14 day supply*** should be offered to allow ample time to assess demonstrated pain relief and tolerability prior to patients acquiring a regular prescription • 16% of physicians suggest that the voucher allow for a full 30 day supply; some request that they have flexibility in writing more than 1 prescription, which would total a 30 day supply
Additional Physician Recommendations for Voucher	• Portion of physicians suggest that voucher that can be used more than once in order to provide maximum pill supply (i.e. if 30 day supply, can have patient try 14 days at one dose and have option to write another 7 day supply at different dose) *"I'd be more willing to use this voucher if it was good for a 30 day supply but I could write a 14 day prescription followed by a 7 day prescription if I needed to alter the dose."* ~ PM&R Pain Specialist

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Appendix

Pain Management and Prescribing Trends - PCP Sample

Screener Data Capture – PCP Sample (n=20)			
Screener Question	**Range**	**Mean**	**Median**
% of practice is allocated to pain management?	10-50%	25%	23%
% of patient population are adults?	70-100%	94%	99%
# chronic pain patients were treated in past month for moderate-to-severe-pain?	30-500 patients	104 patients	78 patients
# patients treated with opioids for some type of pain in typical month?	30-500 patients	118 patients	100 patients
% of opioid Rxs for long-acting oral opioids?	20-90%	44%	38%
# Nucynta Rxs written in past 3 months?	0-50 Rxs	9 Rxs	5 Rxs
# Embeda Rxs written in past 3 months?	0-25 Rxs	5 Rxs	3 Rxs
# Opana ER Rxs written in past 3 months?	0-80 Rxs	10 Rxs	5 Rxs
# Nucynta details in past year?	0-30 rep visits	9 rep visits	6 rep visits
# Embeda details in past year?	0-40 rep visits	4 rep visits	1 rep visit
# Opana ER details in past year?	0-12 rep visits	3 rep visits	2 rep visits

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Appendix

Pain Management and Prescribing Trends – PM&R Pain Specialist Sample

Screener Data Capture –Pain Specialist Sample (Physical Medicine & Rehabilitation [n=10])			
Screener Question	**Range**	**Mean**	**Median**
% of practice is allocated to pain management?	50-100%	87%	97%
% of patient population are adults?	90-100%	98%	99%
# chronic pain patients were treated in past month for moderate-to-severe-pain?	50-400 patients	192 patients	200 patients
# patients treated with opioids for some type of pain in typical month?	50-385 patients	189 patients	160 patients
% of opioid Rxs for long-acting oral opioids?	20-80%	51%	50%
# Nucynta Rxs written in past 3 months?	0-240 Rxs	26 Rxs	4 Rxs
# Embeda Rxs written in past 3 months?	0-120 Rxs	16 Rxs	0 Rxs
# Opana ER Rxs written in past 3 months?	0-300 Rxs	35 Rxs	2 Rxs
# Nucynta details in past year?	0-24 rep visits	8 rep visits	4 rep visits
# Embeda details in past year?	0-18 rep visits	5 rep visits	3 rep visit
# Opana ER details in past year?	0-10 rep visits	3 rep visits	2 rep visits

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Appendix

Pain Management and Prescribing Trends – Anesthesiology Pain Specialist Sample

Screener Data Capture -Pain Specialist Sample (Anesthesiology [n=5])			
Screener Question	**Range**	**Mean**	**Median**
% of practice is allocated to pain management?	50-100%	80%	100%
% of patient population are adults?	95-100%	97%	98%
# chronic pain patients were treated in past month for moderate-to-severe-pain?	200-600 patients	380 patients	300 patients
# patients treated with opioids for some type of pain in typical month?	100-510 patients	232 patients	200 patients
% of opioid Rxs for long-acting oral opioids?	35-100%	58%	50%
# Nucynta Rxs written in past 3 months?	15-100 Rxs	44 Rxs	30 Rxs
# Embeda Rxs written in past 3 months?	4-100 Rxs	40 Rxs	20 Rxs
# Opana ER Rxs written in past 3 months?	20-75 Rxs	41 Rxs	40 Rxs
# Nucynta details in past year?	6-48 rep visits	25 rep visits	12 rep visits
# Embeda details in past year?	1-12 rep visits	5 rep visits	5 rep visits
# Opana ER details in past year?	1-6 rep visits	4 rep visits	5 rep visits

**Note: All Anesthesiology Pain Specialists recruited reported at least 50% of practice is allocated to out-patient care vs. in-patient care consistent with screener.*

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Appendix

Pain Management and Prescribing Trends – Rheumatologist Sample

Screener Data Capture –Rheumatologist Sample (n=5)			
Screener Question	**Range**	**Mean**	**Median**
% of practice is allocated to pain management?	20-90%	61%	66%
% of patient population are adults?	99-100%	100%	100%
# chronic pain patients were treated in past month for moderate-to-severe-pain?	100-200 patients	150 patients	150 patients
# patients treated with opioids for some type of pain in typical month?	60-150 patients	102 patients	100 patients
% of opioid Rxs for long-acting oral opioids?	20-40%	31%	30%
# Nucynta Rxs written in past 3 months?	0-55 Rxs	13 Rxs	3 Rxs
# Embeda Rxs written in past 3 months?	0-5 Rxs	1 Rx	1 Rx
# Opana ER Rxs written in past 3 months?	0-20 Rxs	6 Rxs	2 Rxs
# Nucynta details in past year?	3-12 rep visits	6 rep visits	5 rep visits
# Embeda details in past year?	0-6 rep visits	3 rep visits	3 rep visits
# Opana ER details in past year?	1-5 rep visits	3 rep visits	2 rep visits

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Appendix

Pain Management and Prescribing Trends – Neurologist Sample

Screener Data Capture -Neurologist Sample (n=5)			
Screener Question	**Range**	**Mean**	**Median**
% of practice is allocated to pain management?	25-90%	48%	40%
% of patient population are adults?	90-100%	95%	98%
# chronic pain patients were treated in past month for moderate-to-severe-pain?	40-300 patients	133 patients	100 patients
# patients treated with opioids for some type of pain in typical month?	80-150 patients	106 patients	100 patients
% of opioid Rxs for long-acting oral opioids?	20-80%	44%	40%
# Nucynta Rxs written in past 3 months?	0-20 Rxs	10 Rxs	10 Rxs
# Embeda Rxs written in past 3 months?	0-20 Rxs	11 Rxs	10 Rxs
# Opana ER Rxs written in past 3 months?	0-30 Rxs	14 Rxs	3 Rxs
# Nucynta details in past year?	0-48 rep visits	12 rep visits	6 rep visits
# Embeda details in past year?	0-12 rep visits	5 rep visits	3 rep visits
# Opana ER details in past year?	2-12 rep visits	5 rep visits	4 rep visits

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Appendix

Pain Management and Prescribing Trends – Oncologist Sample

Screener Data Capture –Oncologist Sample (n=5)			
Screener Question	**Range**	**Mean**	**Median**
% of practice is allocated to pain management?	20-80%	49%	35%
% of patient population are adults?	95-100%	99%	100%
# chronic pain patients were treated in past month for moderate-to-severe-pain?	60-100 patients	74 patients	60 patients
# patients treated with opioids for some type of pain in typical month?	60-150 patients	94 patients	85 patients
% of opioid Rxs for long-acting oral opioids?	50-80%	66%	70%
# Nucynta Rxs written in past 3 months?	0-3 Rxs	1 Rx	1 Rx
# Embeda Rxs written in past 3 months?	0-1 Rxs	0 Rx	0 Rx
# Opana ER Rxs written in past 3 months?	0-2 Rxs	1 Rx	1 Rx
# Nucynta details in past year?	0-5 rep visits	2 rep visits	1 rep visit
# Embeda details in past year?	0-1 rep visits	0 rep visits	0 rep visits
# Opana ER details in past year?	0-2 rep visits	1 rep visit	1 rep visit

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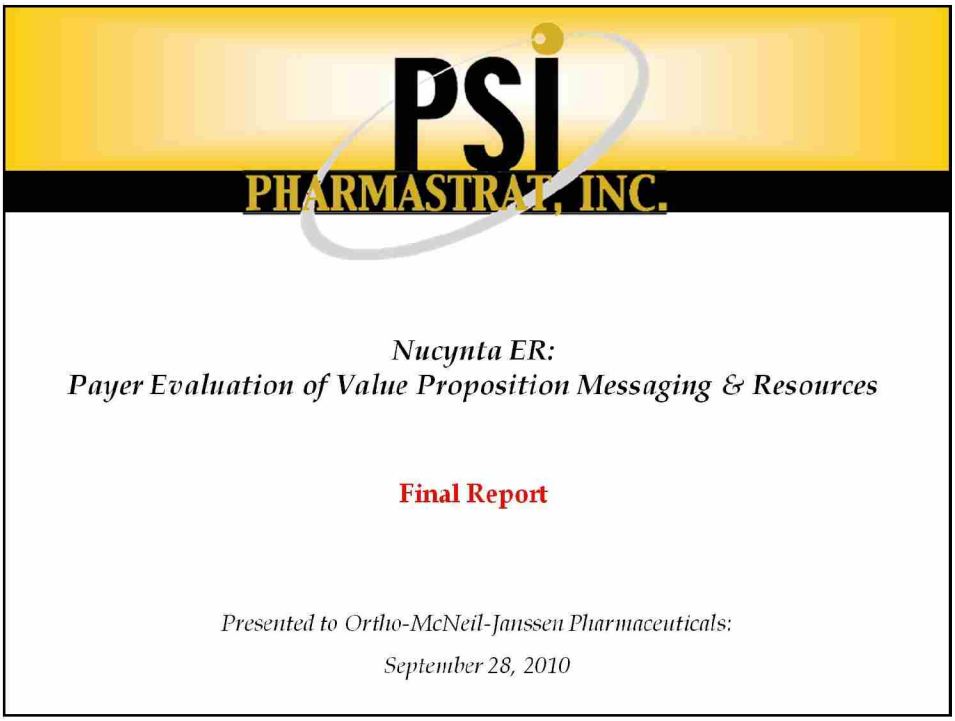
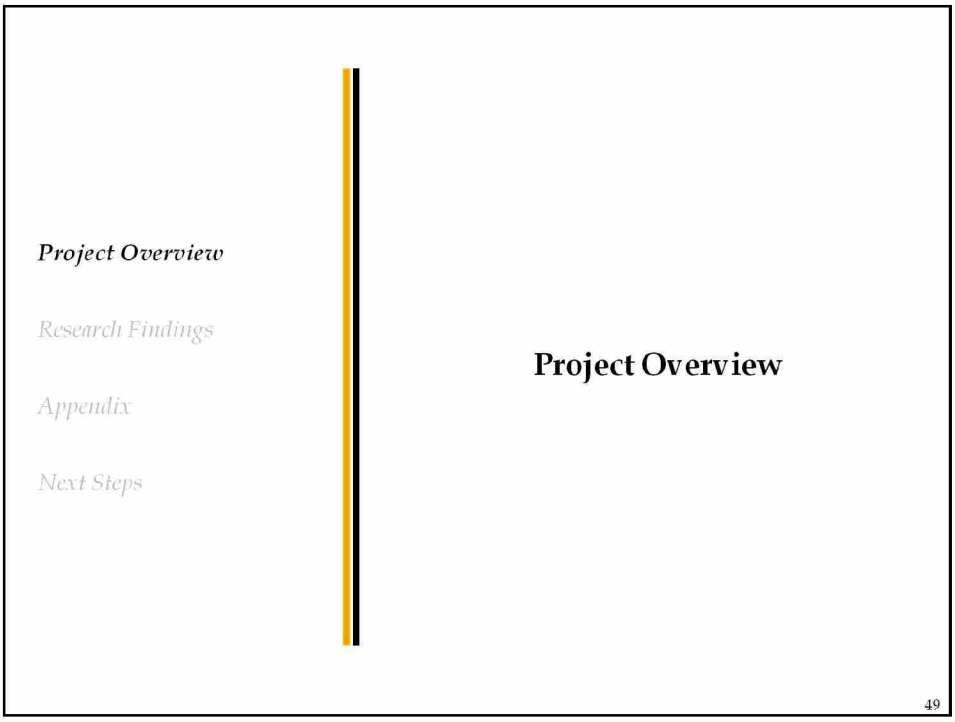

PSI
PHARMASTRAT, INC.
Nucynta ER:
Payer Evaluation of Value Proposition Messaging & Resources
Final Report
Presented to Ortho-McNeil-Janssen Pharmaceuticals:
September 28, 2010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Project Overview

Research Objectives

The primary objective of this research was to obtain payer feedback regarding the Nucynta ER brand value proposition and supporting product attributes and benefits, in order to inform marketing strategies, tactics and messages for Nucynta ER.

Specific Research Questions Included:

- Understanding payers' existing knowledge and perceptions of Nucynta IR
- Gaining payer perceptions of the current chronic pain market
  - Uncovering desired differentiation in the chronic pain market among payers
  - Determining payers' perceived unmet needs in this space
- Obtaining payer feedback on the Nucynta ER target product profile and value claim stimuli
  - Evaluating Nucynta ER clinical attributes by obtaining aided and unaided feedback
  - Obtaining payer critiques and prioritizing value proposition statements
  - Identifying the most compelling value story flow among payers
- Gathering payer feedback on potential Nucynta ER value-added programs
  - Assessing current and potential future partnership opportunities with payers
  - Assessing the OMJP responsible opioid prescribing program

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Project Overview

Methodological Approach

- **Method**: Qualitative Telephone-Depth Interviews (TDIs) designed to last approximately 50 minutes each. TDIs were web-assisted to allow for exposure to a target product profile and complimentary value proposition stimuli.
- **Timing:** Interviews were conducted between August 18th and August 26th, 2010.
- **Sample:** A total sample of forty managed care stakeholders were included in this research. Target respondents included:
  - N=24 Medical Directors
  - N=16 Pharmacy Directors
- **Sampling Criteria**: Adequate sampling of respondents was performed based on screening criteria developed collaboratively between PharmaStrat and OMJP. The following criteria was used:
  - Relative split between OMJP advisory board attendees (targets) vs. non-attendees (non-targets)
  - Predominantly Commercial and Medicare focused managed care organizations
  - Predominantly national and regional focused managed care organizations

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Project Overview

Sample Design

- Of the forty respondents surveyed, half were recruited from the OMJP provided list of previous advisory board attendees. The other half were recruited from leading national and regional managed care organizations.

Target Segment	Target Respondent	Sample Size	Organization	
Advisory Board Attendees	MCO Medical Directors	12	Advocate Health Care AmeriGroup Anthem CenCal Health Health Net of the Northeast Horizon BCBS of New Jersey Humana ODS Health Plan Optima Physicians Health Plan of N Indiana	Premera Blue Cross Presbyterian Health Plan Prodigy Health Group SCAN Health Plan SelectHealth (2) Sharp Healthcare United Healthcare Universal Health Services Wellcare
	MCO Pharmacy Directors	8		
Non-Attendees	MCO Medical Directors	12	Affinity Health Plan Assurant Health Atrius Health BCBS Association BCBS of North Carolina BCBS of Mississippi BCBS of Michigan Bluegrass Family Health Cigna Coventry Healthcare	Geisinger Harvard Pilgrim Healthcare Health Net of California HealthFirst Health Alliance Plan (HAP) Molina Providence Sanford Health Plan Sutter Health United Healthcare
	MCO Pharmacy Directors	8		
Total		40		

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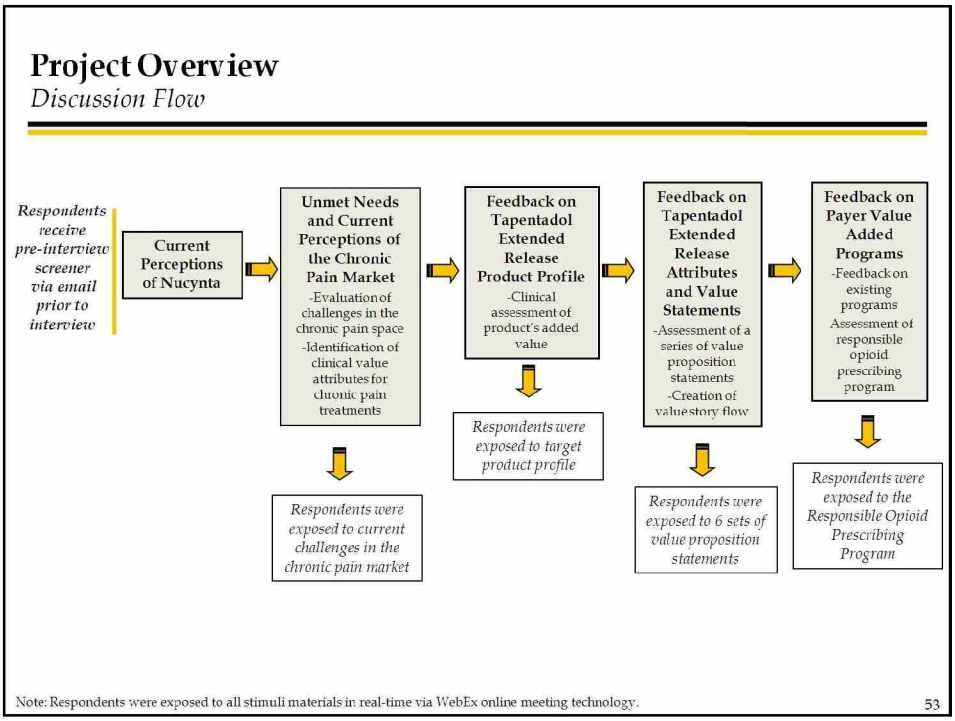

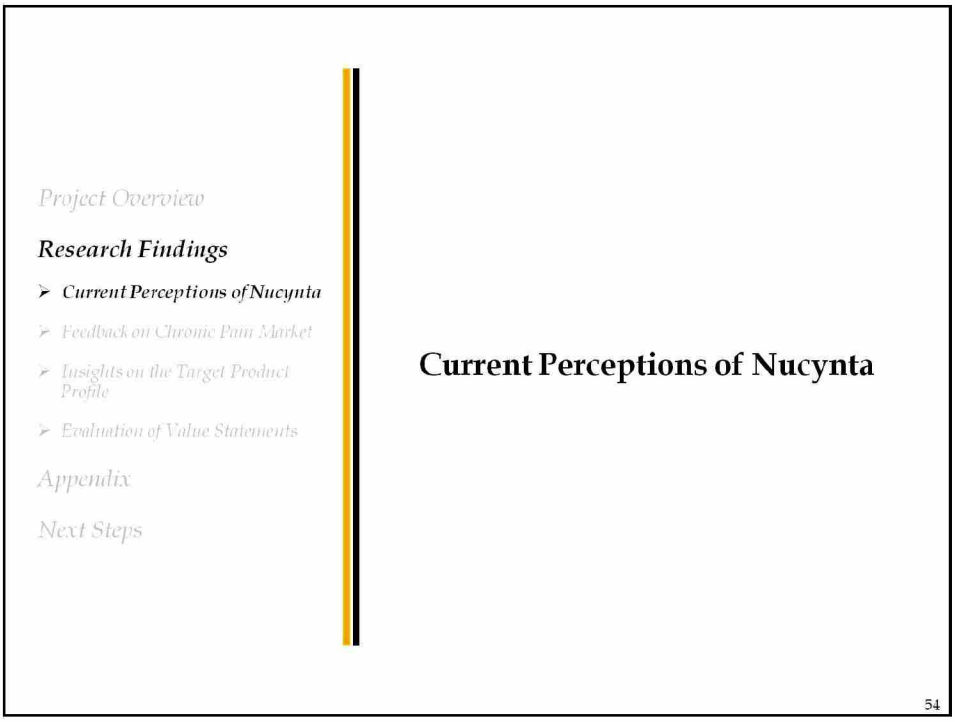
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Current Perceptions of Nucynta

OMJP Company Interactions and Nucynta Recall

Company Interactions:

- Approximately half of respondents surveyed reported having had interactions with an OMJP account manager or clinical liaison.
- Of the 20/40 respondents who were documented as having attended a previous OMJP Nucynta advisory board, only half reported having attended the advisory board and could recall specific information about Nucynta.
- Very few respondents recalled having seen advertisements in any format for Nucynta.

Product Recall:

- Payers recalled the following from previous interactions regarding Nucynta, including:
  - Comparable efficacy to OxyContin (n=22)
  - An improved tolerability profile vs. current short-acting opioid alternatives, especially lower GI side effects (n=16)
  - A unique dual mechanism of action (n=11)

- On average, respondents that attended a previous OMJP payer advisory board were able to communicate more in-depth knowledge associated with the unique characteristics of both Nucynta IR and tapentadol extended release, as compared to non-attendees.

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Current Perceptions of Nucynta

Formulary Management of Nucynta

- Approximately two thirds of health plans surveyed reported having Nucynta on Tier 3, with most providing relatively open access and limited restrictive (PA/SE) criteria.
- Respondents indicated that because the acute pain market is highly saturated with generics, health plans are looking for clinical differentiation with regards to enhanced efficacy in order to warrant preferred tiering of branded agents.
- Respondents have not seen sufficient clinical evidence to support a preferred position for Nucynta, therefore most are using tiering/co-pay differentials to separate the product from less costly generic alternatives.

  "The pain market is highly competitive and largely influenced by available generic options. As a result, we are looking for the demonstration of superior efficacy, as well as a reduced side effect profile in comparison to existing therapies, and we just haven't seen that with Nucynta." - Medical Director

- Thus, payers rely heavily on pricing/contracting agreements for a brand to obtain Tier 2 access.

  "There are plenty of safe, effective and less expensive alternative therapies in this generic driven market, which results in a heavy reliance on cost, contracting and market share. And to be honest, Johnson and Johnson hasn't offered us a contract on this product so why should we advantage it?" - Pharmacy Director

Note: Restrictions are defined as Prior Authorization and Step Edit criteria. Quantity limits are not included in restrictions for this category due to the fact that they are relatively standard on all chronic pain medications.

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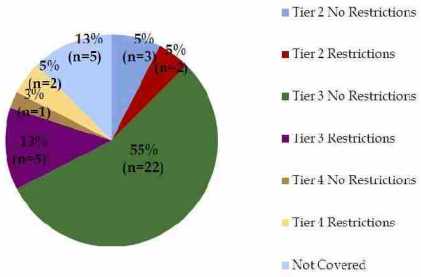
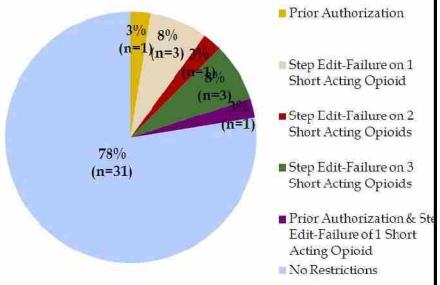
Current Perceptions of Nucynta

Detailed Management of Nucynta

Current Formulary Management of Nucynta
n=40 Respondents Reporting



Prevalence of Restrictions on Nucynta
n=40 Respondents Reporting



Q: What is your current formulary and utilization management strategy for Nucynta?
Note: Restrictions are defined as Prior Authorization and Step Edit Criteria. Quantity limits are not included in restrictions for this category due to the fact that they are relatively standard on all chronic pain medications.

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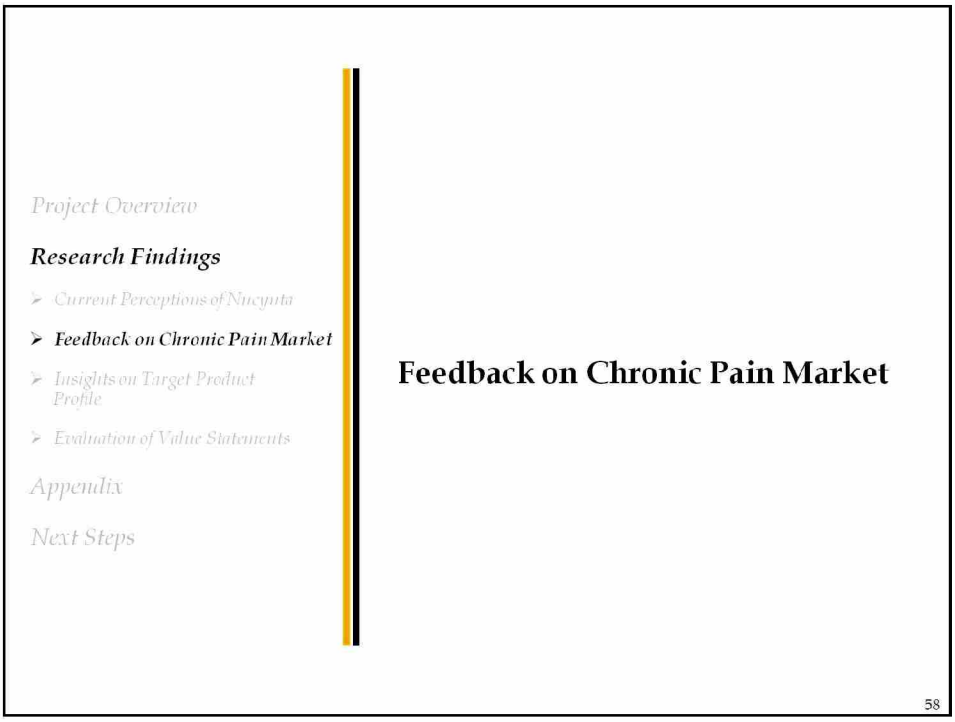

Feedback on Chronic Pain Market

Current and Future Challenges and Unmet Needs

Current Perceptions:

- Respondents were in overall agreement with most statements shared and reported that they provide an accurate depiction of the key issues in the category.
- The one statement that respondents expressed confusion over is the "skepticism toward the benefits of medication" statement, perceiving that it is not skepticism, but rather fear and apprehension around pain treatment that causes concerns.

> *"I believe these statements to be pretty accurate, however, I'm not sure if I agree with the skepticism toward medication benefits. Opioids are efficacious and provide pain relief, however their downfall is the physician and patient fear of using them. Therefore they just get used incorrectly."- Medical Director*

Feedback on Future Changes Anticipated:

- Respondents stressed that many of the unmet needs presented stem from the lack of appropriate physician/patient education on effective pain management.
- Payers believe that if solid pain treatment guidelines and protocols were developed, many of the challenges in the category would begin to be addressed.

> *"Currently, there is a lack of treatment guidelines, resulting in poor provider education and awareness in of both product pharmacology and pain differentiation in the acute and chronic pain space. Over the next few years, I think we will see an increased focus on physician training in pain management."-Medical Director*

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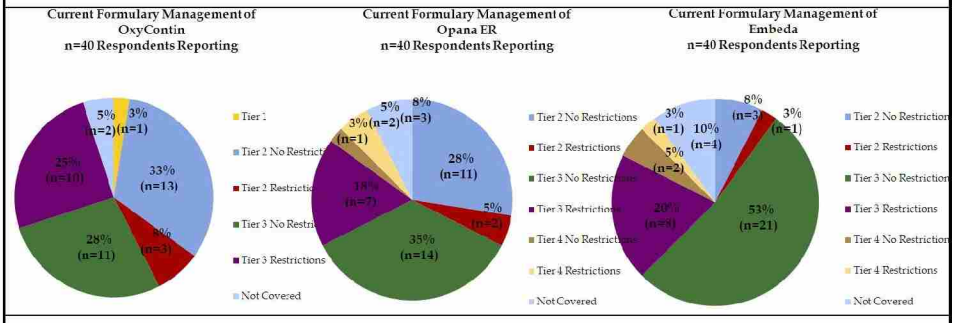
Feedback on Chronic Pain Market

Current Formulary Management of Chronic Pain Treatments

- Lack of significant clinical differentiation among products has lead to management of chronic pain medications being primarily based upon three key attributes: pricing/contracting, physician preference and product demand.
  - Although many respondents reported a lack of satisfaction with OxyContin, they noted that it is often a physicians' 'drug of choice' for chronic pain management, which results in many health plans deciding to offer the brand with unrestricted access.



Q: Please describe in detail how your organization is currently covering the following products: OxyContin, Embeda and Opana ER.
Note: Restrictions are defined as Prior Authorization and Step Edit Criteria. Quantity limits are not included in restrictions for this category due to the fact that they are relatively standard on all acute pain medications.

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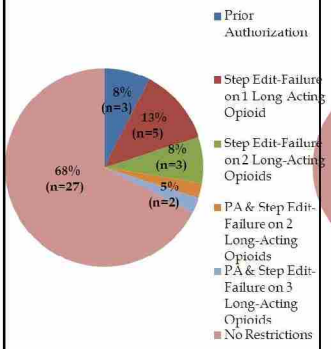
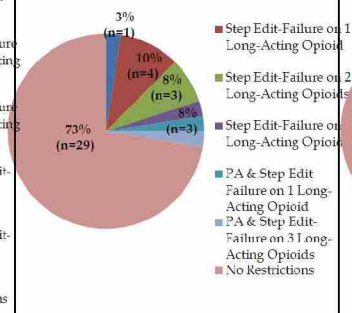
Feedback on Chronic Pain Market

Detailed Management of Chronic Pain Treatments

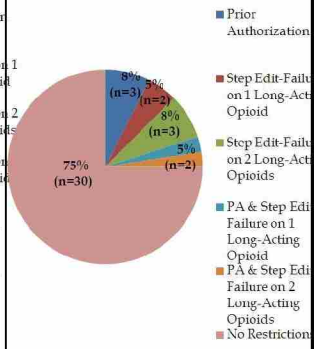
Prevalence of Restrictions for OxyContin n=40 Respondents Reporting



Prevalence of Restrictions for Opana ER n=40 Respondents Reporting



Prevalence of Restrictions for Embeda n=40 Respondents Reporting



Q: What are your current formulary and utilization management strategies for Opana ER, OxyContin and Embeda?
Note: Restrictions are defined as Prior Authorization and Step Edit Criteria. Quantity limits are not included in restrictions for this category due to the fact that they are relatively standard on all acute pain medications.

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Feedback on Chronic Pain Market

Existing Value Added Programs

- Overall, payers were unaware of any value added manufacturer programs that exist in the chronic pain space. Of the small subset of payers who recalled past and current value added programs, the only program recalled by name was Purdue's CS Pure Program for OxyContin.
- Payers prefer not to use manufacturer supported programs as they are perceived to be a conflict of interest. Should a program be warranted in a specific therapeutic area, the health plan would prefer to implement the program internally without involvement from manufacturers.

  "I am really being honest when I tell you that we are not using manufacturer supported programs. As you know, I work for one of the largest national payers, so if we're not using these types of programs, I can assure you that the smaller plans are not using them. There is just so much bias that goes into the programs and they conflict with the nature of what managed care is trying to do." – Pharmacy Director

- The small number of plans who mentioned that they use manufacturer supported programs, recommended that the programs be non-brand specific and more focused on chronic pain management overall.

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Feedback on Chronic Pain Market

Responsible Opioid Prescribing Program Evaluation

- Respondents were generally indifferent to the responsible opioid prescribing program; believing that the resources provided are more directed toward prescribers, and the goals of the program can be accomplished without the involvement of a health plan.

  "The components of this program are nice and will make everyone feel good, but they're not going to make me jump out of my chair. If you think back to the challenges and unmet needs we talked about earlier, almost all of them center around the prescribers. That's where I'm seeing this program that you've showed me is most focused on and that's where it should be focused." – Pharmacy Director

- Payers reported that physician education is the strongest benefit to the program and could potentially work to address some of the unmet needs in the chronic pain market, such as inaccurate pain differentiation and common treatment challenges.

- Payers stressed that the most important way a manufacturer can help in the chronic pain space is to advocate for national guidelines that will begin to push the physician community to establish concrete treatment algorithms, guidelines and best practices to streamline the chronic pain treatment approach.

  "My advice would be for the manufacturer to save their money and spend it instead to improve the overall management of chronic pain. It's absolutely essential that there be guidelines established and no one seems to want to be the one to do it. In my opinion, a manufacturer that puts their hand up to advocate for this is showing a real good faith gesture that will not go unnoticed." – Medical Director

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Insights on Target Product Profile

Perceived Benefits

- Respondents reported the following key advantages, that differentiate tapentadol extended release from existing chronic pain treatments:
  - Increased tolerability with regard to lower GI side effects (n=23)
  - Unique dual mechanism of action (n=19)
  - Potential ability to use an opioid to treat diabetic peripheral neuropathy (n=16)
  - Decreased abuse potential and tamper-resistant properties (n=15)
  - No drug-drug interactions (n=11)
  - Dosage and titration flexibility (n=8)

- The demonstration of comparable efficacy to oxycodone CR is not perceived to be a benefit, however payers did indicate that equivalent efficacy coupled with the additional advantages noted above could make tapentadol extended release a favorable alternative to OxyContin, as long as there is physician uptake and demand for the product.

  "I am impressed by this product's comparable efficacy to OxyContin. Plus it has the reduced side effect profile and greater tolerability in relation to OxyContin, which will lead to better patient compliance and persistence. The tamper resistant attribute decreases the street value of the product , which is an added benefit, considering OxyContin has a high risk of abuse and diversion."- Medical Director

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Insights on Target Product Profile

Areas of Question/Concern

- Upon exposure to the product profile, respondents pointed out the following areas of question/concern:
  - Data on study size, patient types and discontinuation rates - payers communicated that clarification on the details of the study would allow for increased credibility to support the results of the trial

    "I am questioning the number of people involved in the clinical trials. Plus, I'd want to know what types of patients they are. Did they stay on therapy? Did they drop out? If so, why did they drop out? These are all valid questions that I would ask when I am talking to my Account Manager. So, I think further details are required in order to get an accurate perception of the trial results."- Medical Director

  - Inclusion of quantifiable statistics on clinical trial data vs. oxycodone CR
  - Further information on whether there is a maximum daily dosage of the product, due to dose escalation concerns within the category
  - Further data on the DPN indication in terms of efficacy vs. existing treatment options

    "This indication is very very intriguing to me. Being that most opioids are not effective against DPN, this attribute could be a clinical advantage for the product, offering a broader range of pain coverage. However, I would be curious to see how this would compare to current therapies with this indication, for example, gabapentin."- Pharmacy Director

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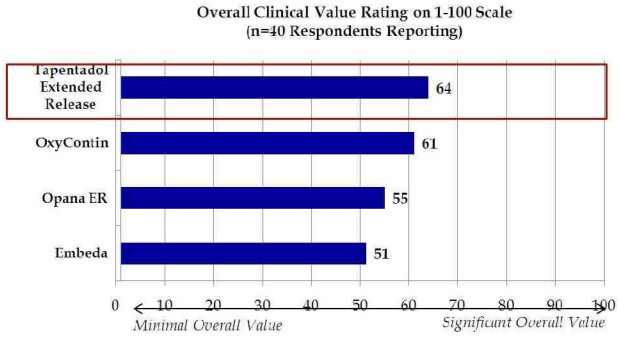
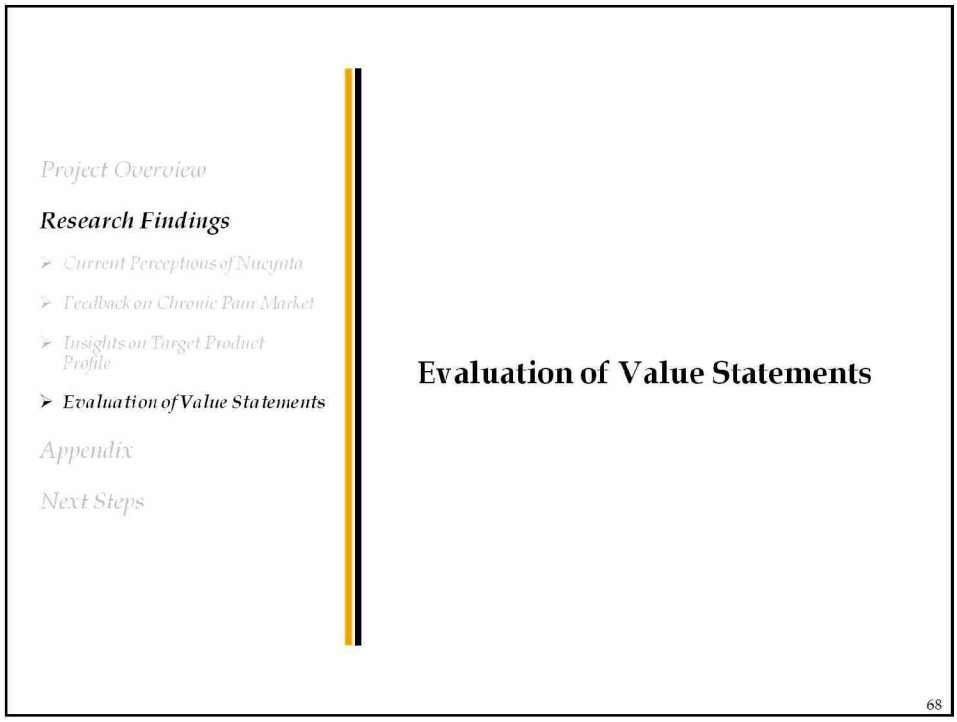
Insights on Target Product Profile

Perceived Clinical Value of Tapentadol Extended Release vs. Existing Therapies

- Respondents rated tapentadol extended release as offering slightly more clinical value than OxyContin, Opana ER and Embeda, due to tapentadol extended release's perceived benefits.
- However, respondents cautioned that the cost of tapentadol extended release will need to be at or below the cost of current treatment options in order to fully substantiate the perceived clinical value of the product's benefits.



Q: How would you rate the overall clinical value of each product on a scale from 1-100, where a "1" means "this product offers minimal overall clinical value to my organization" and a "100" means "this product offers significant overall clinical value to my organization?" 67



Evaluation of Value Statements

Summary of Payer Exercises

- In order to determine the most effective value proposition statements to be shared with the payer audience in support of tapentadol extended release, respondents were asked for both qualitative and quantitative feedback on the following six attributes of the product:
    1. Mechanism of Action
    2. Efficacy
    3. Chronic Low Back Pain
    4. Safety
    5. Tolerability
    6. Dosing and Administration
- Respondents were asked to rank order the series of value proposition statements from most preferable to least preferable when considering moderate to severe chronic pain. This exercise was completed within each of the six sections.
- Respondents were then asked to allocate a total of 100 points across the statements within each of the six sections in order to determine how strongly they valued each statement as compared to the others.
- Qualitative feedback on the strengths and weaknesses of each statement was then received.
- The following slides provide detailed feedback on payer perceptions of the overall value statements in support of tapentadol extended release.

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Evaluation of Value Statements

Mechanism of Action

Value Statement	Number of Mentions by Rank Order 1-4 (n=40 Respondents Reporting)	Average Rank	Average Points
M-2 *"The combined activity of norepinephrine-reuptake inhibition and mu-opioid receptor…"*	19 / 10 / 10 / 1	1.8	37
M-4 *"With a MOA that provides analgesic activity across the two key pain pathways…"*	14 / 15 / 5 / 6	2.1	30
M-1 *"Tapentadol, a single agent with two mechanisms of action…"*	4 / 12 / 16 / 8	2.7	21
M-3 *"While traditional opioids work predominantly along the ascending pathway…"*	3 / 3 / 9 / 25	3.4	12

■ Rank Order 1 ■ Rank Order 2 ■ Rank Order 3 ■ Rank Order 4

Q1: How would you prioritize the value proposition statements from most preferable to least preferable when considering moderate to severe chronic pain?
Q2: How would you distribute 100 points across these two statements? The more points you allocate to a statement, the more preferable it is to you. 70

Evaluation of Value Statements

Mechanism of Action

- Payers preferred statement M-2 due to its specific mention of a *combined mechanism of action, equivalent pain control to OxyContin*, coupled with a *reduced side-effect profile*. Medical Directors tended to favor this statement over Pharmacy Directors, seeing it as the most scientifically focused.

  "This statement shows how different factors in the product's unique mechanism of action translate into value-added benefits, including the reduction of side effects and equi-analgesia to OxyContin."- Pharmacy Director

- Respondents chose statement M-4 as a close second, as it further specifies the product's *activity across the two key pain pathways*. In addition, M-4 includes mention of efficacy *across a broad range of pain models and patient types*, which payers perceived to be an important component for chronic pain medications.

Note: See slide 46 in the appendix for segmentation by pharmacy vs. medical. 71

Evaluation of Value Statements

Efficacy

Value Statement	Number of Mentions by Rank Order 1-4 (n=40 Respondents Reporting)	Average Rank	Average Points
E-4 "Consistent, low incidence of GI side effects enabled more Tapentadol Extended Release…"	15 | 15 | 5 | 5	2	35
E-3 "In a 1-year study, patients taking Tapentadol Extended Release with moderate to severe…"	14 | 12 | 7 | 7	2.2	29
E-1 "Tapentadol Extended Release has been proven effective across multiple pain models…"	9 | 6 | 21 | 4	2.5	21
E-2 "Tapentadol Extended Release offers the confidence of analgesic efficacy across…"	2 | 7 | 7 | 24	3.3	15

Q1: How would you prioritize the value proposition statements from most preferable to least preferable when considering moderate to severe chronic pain?
Q2: How would you distribute 100 points across these two statements? The more points you allocate to a statement, the more preferable it is to you. 72

Evaluation of Value Statements

Efficacy

- Payers surveyed preferred statements E-4 and E-3, as E-4 expresses the product's most valuable characteristics, including its *reduced side effect profile compared to oxycodone CR* and the potential for *reduced medical resource utilization.*

  "E-4 really gives me the impression that this product is going to give OxyContin a run for its money. It works just as well, its more tolerable and it may save the healthcare system money. These are compelling claims. What remains to be seen is whether or not they are true. – Pharmacy Director

- E-3 not only addresses the *reduced medical resource utilization,* but also specifies efficacy in *two specific types of pain: osteoarthritis of the knee and low back pain.* The *fewer dosage adjustments* claim also resonated well with payers, as they perceive that it will lead to reduced pharmacy utilization.

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Evaluation of Value Statements

Chronic Low Back Pain

Value Statement	Number of Mentions by Rank Order 1-2 (n=40 Respondents Reporting)	Average Rank	Average Points
B-1 *"Tapentadol Extended Release offers analgesic efficacy comparable to that of oxycodone CR…"*	22 / 18	1.5	55
B-2 *"According to post-hoc analysis, Tapentadol Extended Release was better tolerated…"*	18 / 22	1.6	45

■ Rank Order 1 ■ Rank Order 2

Q1: How would you prioritize the value proposition statements from most preferable to least preferable when considering moderate to severe chronic pain?
Q2: How would you distribute 100 points across these two statements? The more points you allocate to a statement, the more preferable it is to you. 74

Evaluation of Value Statements

Chronic Low Back Pain

- Payers preferred statement B-1 due to its specific focus on *chronic low back pain*, which respondents indicated is the *most common and costly type of chronic pain*. Coupled with tapentadol extended release's *improved tolerability and comparable efficacy to oxycodone CR*, B-1 resonated well with payers.
  - *"Chronic low back pain is a huge area of spend for our organization. I think that this statement is an important one to include after efficacy across multiple pain models and patient types has been addressed, because it shows that not only does tapentadol extended release work across the board, it also works in the largest niche area where pain control is needed." - Medical Director*
- While payers liked the specificity of *opioid-naïve patients* in statement B-2 and the strength of the *persistence on therapy*, they expressed a strong dislike for the *post-hoc analysis* component of the statement. This term made payers question the credibility of the statement.
  - *"Anytime I see a mention of post-hoc analysis, I will completely discount the results. The Account Managers that I see know better than to come to me with this type of data. To me, it doesn't hold a shred of value. This term is a slippery slope for managed care, so I'd really recommend reconsidering its use in the statement." – Pharmacy Director*
- In addition, payers questioned why statement B-2 did not make specific mention of *chronic low back pain* when it is included in the section geared towards that specific subset of pain.

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Evaluation of Value Statements

Safety

Value Statement	Number of Mentions by Rank Order 1-5 (n=40 Respondents Reporting)	Average Rank	Average Points
S-4 *"Tapentadol Exiended Release offers a favorable tolerability profile that older patients…"*	17 | 10 | 7 | 4 | 2	2.1	28
S-1 *"86.2% of Tapentadol Extended Release…"*	13 | 10 | 7 | 4 | 6	2.5	22
S-5 *"Tapentadol Extended Release is associated with greaier persistency and higher rates of…"*	5 | 6 | 7 | 7 | 15	3.5	16
S-2 *"Tapentadcl Extended Release is not metabolized through the cytochrome…"*	3 | 7 | 8 | 13 | 9	3.5	16
S-3 *"The tamper-resistant formulation…"*	2 | 7 | 11 | 12 | 8	3.4	18

■ Rank Order 1 ■ Rank Order 2 ■ Rank Order 3 ■ Rank Order 4 ■ Rank Order 5

Q1: How would you prioritize the value proposition statements from most preferable to least preferable when considering moderate to severe chronic pain?
Q2: How would you distribute 100 points across these two statements? The more points you allocate to a statement, the more preferable it is to you. 76

Evaluation of Value Statements

Safety

- Payers preferred statement S-4, as they perceived *tolerability of opioids in the elderly* to be a difficult to manage issue associated with chronic pain treatment. Payers with Medicare members especially liked this statement. Medical Directors tended to prefer this statement over Pharmacy Directors, often due to their clinical background in actually experiencing GI tolerability issues in the elderly first hand.

  "Opioids pose tolerability issues to patients. However, the over 65 population are especially susceptible to these concerns. Many of the elderly patients fall off treatment because of the GI issues. So I think this is an important population to target since this medication has something unique to offer." – Medical Director

- Payers also expressed favorable perceptions around statement S-1 due to the quantifiable nature of the statement. The ability for patients to *discontinue treatment without withdrawal* was also seen as important due to the perceived high degree of switching that occurs in the chronic pain category.

  "Lack of withdrawal is huge. My background is in pain management, so I know how often patients will go from one medication to another. This easy transition will give physicians a greater confidence in using this medication." – Medical Director

Note: See slide 52 in the appendix for segmentation by pharmacy vs. medical.

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Evaluation of Value Statements

Tolerability

Value Statement	Number of Mentions by Rank Order 1-2 (n=40 Respondents Reporting)	Average Rank	Average Points
T-1 *"In a 52-week safety study patients receiving Tapentadol Extended Release experienced…"*	32 / 8	1.2	61
T-2 *"More Tapentadol Extended Release patients completed treatment and experienced…"*	8 / 32	1.8	39

0 5 10 15 20 25 30 35 40

Most Preferable *Least Preferable*

■ Rank Order 1 ■ Rank Order 2

Q1: How would you prioritize the value proposition statements from most preferable to least preferable when considering moderate to severe chronic pain?
Q2: How would you distribute 100 points across these two statements? The more points you allocate to a statement, the more preferable it is to you. 78

Evaluation of Value Statements

Tolerability

- Payers clearly preferred statement S-1 over statement S-2. Respondents reported that they value quantifiable results in regards to the ***reduction of adverse events*** in comparison to oxycodone CR. In addition, specific percentages allowed for a clearer understanding of the clinical outputs.

  "S-1 is far superior to S-2. I've been asking for data every time I see a statement and now here it is. This is what managed care wants to see." – Pharmacy Director

  "This statement references the specific incidence of side-effects vs. the competition and it also goes a step further and references the particular study and length of the study. It's very compelling." – Medical Director

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Evaluation of Value Statements

Dosing and Administration (not incl. DA-4)

Value Statement	Number of Mentions by Rank Order 1-3 (n=34 Respondents Reporting)	Average Rank	Average Points
DA-1 *"Tapentadol Extended Release is available in 5 doses strengths…"*	22 / 10 / 2	1.4	42
DA-3 *"Simple conversion calculations make it easy for providers to switch…"*	9 / 19 / 6	1.9	37
DA-2 *"Tapentadol Extended Release has been studied in multiple pain conditions in doses up to…"*	3 / 5 / 26	2.7	21

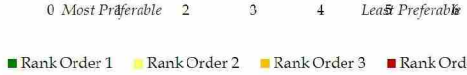
■ Rank Order 1 ■ Rank Order 2 ■ Rank Order 3

Note: 34/40 Respondents Reporting on DA-1, 2 and 3. Results from remaining 6 respondents are presented on the following slide.
Q1: How would you prioritize the value proposition statements from most preferable to least preferable when considering moderate to severe chronic pain?
Q2: How would you distribute 100 points across these two statements? The more points you allocate to a statement, the more preferable it is to you. 80

Evaluation of Value Statements

Dosing and Administration (incl. DA-4)

Value Statement	Number of Mentions by Rank Order 1-4 (n=6 Respondents Reporting)	Average Rank	Average Points
DA-3 "Simple conversion calculations make it easy for providers to switch…"	3 | 2 | 1	1.7	30
DA-1 "Tapentadol Extended Release is available in 5 doses strengths…"	2 | 1 | 2 | 1	2.3	27
DA-4* "Based on clinical trials, dosing for oxycodone IR or CR can be converted…"	1 | 2 | 2 | 1	2.5	28
DA-2 "Tapentadol Extended Release has been studied in multiple pain conditions in doses up to…"	1 | 1 | 4	3.5	18



■ Rank Order 1 ■ Rank Order 2 ■ Rank Order 3 ■ Rank Order 4

*Note: Statement DA-4 was a late addition to the research and was only tested with 6/40 respondents.
Q1: How would you prioritize the value proposition statements from most preferable to least preferable when considering moderate to severe chronic pain?
Q2: How would you distribute 100 points across these two statements? The more points you allocate to a statement, the more preferable it is to you. 81

Evaluation of Value Statements

Dosing and Administration

- Payers preferred statement DA-1 as it provided the feeling of ease of use and ***flexibility of dosing***, as well as clearly quantified the specific ***dosage strengths*** and range available. However, respondents noted that the statement should include mention of not only dosing, but how the product is administered (i.e. in tablet form).

  "This statement says all we need to know and it says it clearly and succinctly. It makes me confident that physicians will appreciate the flexibility of the product, and having the range of dosage availability in one place makes it easy for me to recall as a pharmacy director." – Pharmacy Director

- Feedback on statement DA-2 indicated that payers are not always clearly interpreting the message that there is a maximum daily dosage of tapentadol extended release available. However, when probed on this, payers indicated that this is an important statement. Payers recommend using the term ***maximum daily dosage*** as opposed to ***studied up to 500 mg per day***, and including the maximum daily dosage of 500 mg as a complimentary addition.

  "The concept of maximum daily dosage is an important message, but right now it's not coming across clearly from this statement. The wording is awkward and unclear. " – Medical Director

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Evaluation of Value Statements

Optimal Value Story Components

- Payers were in agreement that the initial order in which the statements were presented was the most effective story flow. This is due to the way in which medications are evaluated at P&T.
- Across both the pharmacy and medical audiences, the following key components were recommended for inclusion in the overall managed care value story :
  - A pointed message around the uniqueness/specificity of the dual mechanism of action and how that ties back to a reduced side-effect profile and ultimately greater persistence on therapy
  - An initial focus on efficacy across a broad range of patient types/pain models, followed by a set of complimentary follow-up statements around efficacy in specific areas, such as: chronic low back pain, osteoarthritis, elderly patients and opioid-naïve patients
  - A specific focus on tolerability/adverse events as compared to oxycodone CR, especially gastrointestinal related events
  - A mention of quantifiable data to support any claims on efficacy, side-effect reduction or cost offsets, especially reduced medical resource utilization
  - An indication that the product will be easy and flexible for physicians to administer
- Feedback on the value statements overall was relatively consistent across both pharmacy and medical stakeholders, thus the creation of one comprehensive value story for the managed care audience is recommended.

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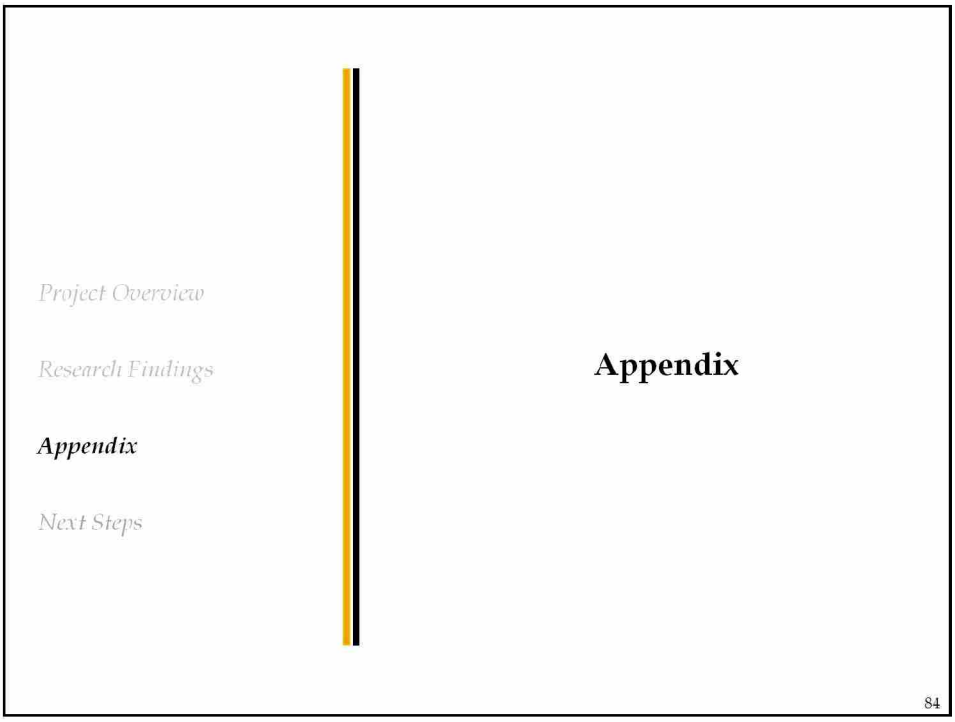

Appendix

Executive Summary

Current Perceptions of Nucynta

- Most payers surveyed were familiar with Nucynta and when asked what stood out about the product, recalled consistent attributes, including: comparable efficacy to OxyContin, an improved tolerability profile vs. current short-acting opioid alternatives, especially with regard to lower GI side effects and a unique dual mechanism of action.
- The majority of plans surveyed are offering Nucynta on Tier 3 with relatively open access. Most respondents noted that they have not seen sufficient clinical evidence to support a preferred position for Nucynta, therefore most are using tiering/co-pay differential to separate the product from less costly generic alternatives used to treat acute pain.

Feedback on Chronic Pain Market

- Respondents agreed that significant challenges and unmet needs exist with regards to chronic pain management, and stressed that many stem from the lack of appropriate physician/patient education on effective pain management. Payers believe that if solid pain treatment guidelines and protocols were developed, many of the challenges in the category would begin to be addressed.
- Payer feedback indicated that management of chronic pain medications is primarily based upon three key attributes: pricing/contracting, physician preference and product demand. Because payers do not perceive significant clinical differentiation exists amongst treatment options, the performance on these three attributes often accounts for the difference between a Tier 2 vs. a Tier 3 brand.

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Appendix

Executive Summary

Insights on Target Product Profile

- Upon exposure to the product profile, respondents reported the following key advantages, in order of number of mentions, that differentiate tapentadol extended release from existing chronic pain treatments: increased tolerability with regard to lower GI side effects, unique dual mechanism of action, potential ability to use an opioid to treat diabetic peripheral neuropathy, decreased abuse potential and tamper-resistant properties, no drug-drug interactions and dosage and titration flexibility.
- When asked to quantify the clinical value of tapentadol extended release relative to existing chronic pain treatments, respondents rated the product as offering slightly more clinical value relative to the long-acting opioid reference set tested, which included OxyContin, Opana ER and Embeda.
- Areas of the product profile where respondents had requests for additional information included: data on study size, patient types and discontinuation rates, inclusion of quantifiable statistics on clinical trial data vs. oxycodone CR, further information on whether there would be a maximum daily dosage of the product and further data on the DPN indication in terms of efficacy vs. existing treatment options

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Appendix

Executive Summary

Evaluation of Value Statements

- Upon being exposed to complimentary value statements in support of tapentadol extended release, the following statements resonated most with payers:
  - *Mechanism of Action*: M-2 and M-4 which specify the product's "combined mechanism of action and activity across two key pain pathways"
  - *Efficacy*: E-3 and E-4 which point to "decreased medical resource utilization" and "reduced side-effects compared to OxyContin"
  - *Chronic Low Back Pain*: B-1 which specifically focuses on "chronic low back pain," which payers note is the most common and most costly type of pain
  - *Safety*: S-4 and S-1 because of the mention of "tolerability in the elderly" and quantifiable statistics on "discontinuation without withdrawal"
  - *Tolerability*: T-1 which indicates specific and quantifiable percentages on various common "GI adverse events"
  - *Dosing and Administration*: DA-1 which provides the feeling of "ease of use and flexibility of dosing," while also specifying specific strengths and range of dosing available
- Overall, feedback on the value statements was relatively consistent across both pharmacy and medical stakeholders, thus the creation of one comprehensive value story for the managed care audience is recommended.

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Appendix

Executive Summary

Discussion of Payer Value Added Programs

- Overall, payers are unaware of any value added manufacturer programs that exist in the chronic pain space and indicated that their plans generally prefer not to use manufacturer supported programs as they are perceived to be a conflict of interest.
- When presented with information on the Responsible Opioid Prescribing Program, payers surveyed were generally indifferent, believing that the resources provided are more directed toward prescribers, and the goals of the program can be accomplished without the involvement of a health plan.
- Payers reported that physician education is the strongest benefit to the program and can potentially work to address some of the unmet needs in the chronic pain market, such as inaccurate pain differentiation and common treatment challenges.
- Beyond value added programs for physicians, payers stressed that the most important way a manufacturer can help in the chronic pain space is to advocate for national guidelines that will begin to push the physician community to establish concrete treatment algorithms, guidelines and best practices to streamline the chronic pain treatment approach.

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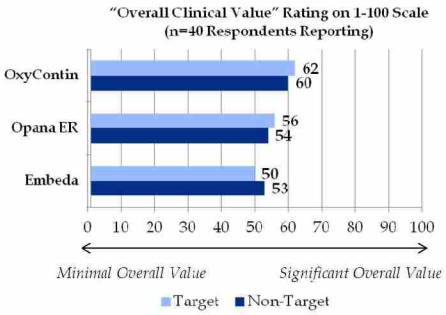
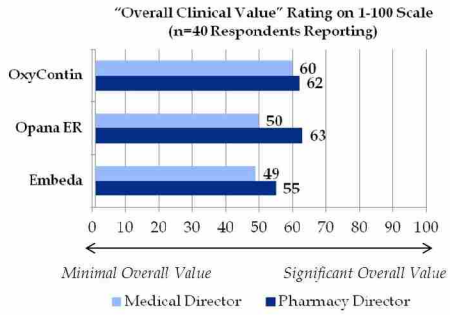
Appendix

Perceived Clinical Value of Chronic Pain Treatments – By Segment





Q: How would you rate the overall clinical value of each product on a scale from 1-100, where a "1" means "this product offers minimal overall clinical value to my organization" and a "100" means "this product offers significant overall clinical value to my organization?"

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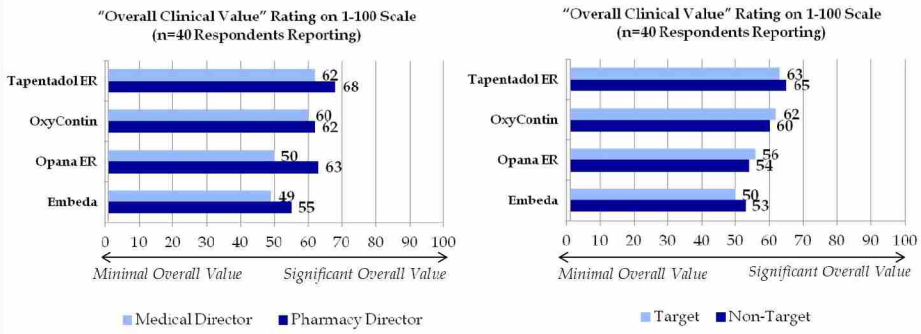
Appendix

Perceived Clinical Value of Tapentadol Extended Release – By Segment



Q: How would you rate the overall clinical value of Tapentadol Extended Release on a scale from 1-100, where a "1" means "this product offers minimal overall clinical value to my organization" and a "100" means "this product offers significant overall clinical value to my organization?"

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Appendix

Feedback on Value Statements- Mechanism of Action – By Pharmacy vs. Medical

Value Statement	Target Segment	Number of Mentions by Rank Order 1-4 Medical Director vs. Pharmacy Director (n=40 Respondents Reporting)	Average Rank	Average Points
M-2 *"The combined activity of norepinephrine-reuptake inhibition and mu-opioid receptor…"*	Medical Director	13 6 5	1.7	39
	Pharmacy Director	6 4 5 1	2.1	34
M-4 *"With a MOA that provides analgesic activity across the two key pain pathways…"*	Medical Director	7 10 2 5	2.2	29
	Pharmacy Director	7 5 3 1	1.9	32
M-1 *"Tapentadol, a single agent with two mechanisms of action…"*	Medical Director	3 5 12 4	2.7	21
	Pharmacy Director	1 7 4 4	2.7	21
M-3 *"While traditional opioids work predominantly along the ascending pathway…"*	Medical Director	1 3 5 15	3.4	11
	Pharmacy Director	2 4 10	3.4	13

Q1: How would you prioritize the value proposition statements from most preferable to least preferable when considering moderate to severe chronic pain?
Q2: How would you distribute 100 points across these two statements? The more points you allocate to a statement, the more preferable it is to you.

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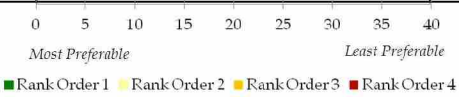
Appendix

Feedback on Value Statements- Mechanism of Action – By Target vs. Non-Target

Value Statement	Target Segment	Number of Mentions by Rank Order 1-4 Target vs. Non-Target (n=40 Respondents Reporting)	Average Rank	Average Points
M-2 *"The combined activity of norepinephrine-reuptake inhibition and mu opioid receptor…"*	Target	11 3 5 1	1.8	40
	Non-Target	8 7 5	1.9	34
M-4 *"With a MOA that provides analgesic activity across the two key pain pathways…"*	Target	5 7 4 4	2.4	25
	Non-Target	9 8 1 2	1.8	35
M-1 *"Tapentadol, a single agent with two mechanisms of action…"*	Target	2 9 6 3	2.5	22
	Non-Target	2 3 10 5	2.9	20
M-3 *"While traditional opioids work predominantly along the ascending pathway…"*	Target	2 1 5 12	3.4	13
	Non-Target	1 2 4 13	3.5	12



Q1: How would you prioritize the value proposition statements from most preferable to least preferable when considering moderate to severe chronic pain?
Q2: How would you distribute 100 points across these two statements? The more points you allocate to a statement, the more preferable it is to you. 92

Appendix

Feedback on Value Statements- Efficacy – By Pharmacy vs. Medical

Value Statement	Target Segment	Number of Mentions by Rank Order 1-4 Medical Director vs. Pharmacy Director (n=40 Respondents Reporting)	Average Rank	Average Points
E-4 *"Consistent, low incidence of GI side effects enabled more Tapentadol Extended Release…"*	Medical Director	10 7 4 3	2	35
	Pharmacy Director	5 8 12	2	34
E-3 *"In a 1-year study, patients taking Tapentadol Extended Release with moderate to severe…"*	Medical Director	8 7 4 5	2.3	30
	Pharmacy Director	6 5 3 2	2.1	28
E-1 *"Tapentadol Extended Release has been proven effective across multiple pain models…"*	Medical Director	5 5 11 3	2.5	20
	Pharmacy Director	4 1 10 1	2.5	22
E-2 *"Tapentadol Extended Release offers the confidence of analgesic efficacy across…"*	Medical Director	1 5 5 13	3.3	15
	Pharmacy Director	2 2 11	3.4	16

Q1: How would you prioritize the value proposition statements from most preferable to least preferable when considering moderate to severe chronic pain?
Q2: How would you distribute 100 points across these two statements? The more points you allocate to a statement, the more preferable it is to you.

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Appendix

Feedback on Value Statements- Efficacy – By Target vs. Non-Target

Value Statement	Target Segment	Number of Mentions by Rank Order 1-4 Target vs. Non-Target (n=40 Respondents Reporting)	Average Rank	Average Points
E-4 *"Consistent, low incidence of GI side effects enabled more Tapentadol Extended Release…"*	Target	8 8 1 3	2.0	37
	Non-Target	7 7 4 2	2.1	33
E-3 *"In a 1-year study, patients taking Tapentadol Extended Release with moderate to severe…"*	Target	7 4 4 5	2.4	27
	Non-Target	7 8 3 2	2	31
E-1 *"Tapentadol Extended Release has been proven effective across multiple pain models…"*	Target	4 4 11 1	2.5	21
	Non-Target	5 2 10 3	2.6	21
E-2 *"Tapentadol Extended Release offers the confidence of analgesic efficacy across…"*	Target	1 4 4 11	3.3	14
	Non-Target	1 3 3 13	3.4	16

Q1: How would you prioritize the value proposition statements from most preferable to least preferable when considering moderate to severe chronic pain?
Q2: How would you distribute 100 points across these two statements? The more points you allocate to a statement, the more preferable it is to you.

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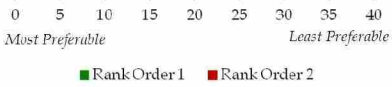
Appendix

Feedback on Value Statements- Chronic Low Back Pain – By Pharmacy vs. Medical

Value Statement	Target Segment	Number of Mentions by Rank Order 1-2 Medical Director vs. Pharmacy Director (n=40 Respondents Reporting)	Average Rank	Average Points
B-1 *"Tapentadol Extended Release offers analgesic efficacy comparable to that of oxycodone CR…"*	Medical Director	12 / 12	1.5	54
	Pharmacy Director	10 / 6	1.4	58
B-2 *"According to post-hoc analysis, Tapentadol Extended Release was better tolerated…"*	Medical Director	12 / 12	1.5	46
	Pharmacy Director	6 / 10	1.6	43

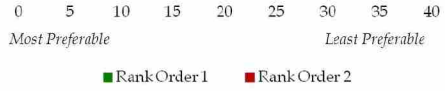


Q1: How would you prioritize the value proposition statements from most preferable to least preferable when considering moderate to severe chronic pain?
Q2: How would you distribute 100 points across these two statements? The more points you allocate to a statement, the more preferable it is to you. 95

Appendix

Feedback on Value Statements- Chronic Low Back Pain – By Target vs. Non-Target

Value Statement	Target Segment	Number of Mentions by Rank Order 1-2 Target vs. Non-Target (n=40 Respondents Reporting)	Average Rank	Average Points
B-1 *"Tapentadol Extended Release offers analgesic efficacy comparable to that of oxycodone CR…"*	Target	10 / 10	1.5	57
	Non-Target	12 / 8	1.4	54
B-2 *"According to post-hoc analysis, Tapentadol Extended Release was better tolerated…"*	Target	10 / 10	1.5	43
	Non-Target	8 / 12	1.6	47



■ Rank Order 1 ■ Rank Order 2

Q1: How would you prioritize the value proposition statements from most preferable to least preferable when considering moderate to severe chronic pain?
Q2: How would you distribute 100 points across these two statements? The more points you allocate to a statement, the more preferable it is to you. 96

Appendix

Feedback on Value Statements- Safety – By Pharmacy vs. Medical

Value Statement	Target Segment	Number of Mentions by Rank Order 1-5 Medical Director vs. Pharmacy Director (n=40 Respondents Reporting)	Average Rank	Average Points
S-4 *"Tapentadol Extended Release offers a favorable tolerability profile that older patients…"*	Medical Director	11 6 4 2	2.0	30
	Pharmacy Director	6 4 3 3	2.2	25
S-1 *"86.2% of Tapentadol Extended Release…"*	Medical Director	6 7 3 4 4	2.7	22
	Pharmacy Director	7 3 4 2	2.2	23
S-5 *"Tapentadol Extended Release is associated with greater persistency and higher rates of…"*	Medical Director	4 4 3 5 8	3.4	16
	Pharmacy Director	1 2 4 2 7	3.8	17
S-2 *"Tapentadol Extended Release is not metabolized through the cytochrome…"*	Medical Director	1 5 4 8 6	3.5	14
	Pharmacy Director	2 2 4 5 3	3.3	17
S-3 *"The tamper-resistant formulation…"*	Medical Director	2 2 10 6 4	3.3	18
	Pharmacy Director	5 1 6 4	3.6	17

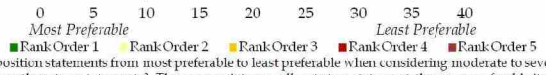
■Rank Order 1 ■Rank Order 2 ■Rank Order 3 ■Rank Order 4 ■Rank Order 5

Q1: How would you prioritize the value proposition statements from most preferable to least preferable when considering moderate to severe chronic pain?
Q2: How would you distribute 100 points across these two statements? The more points you allocate to a statement, the more preferable it is to you. 97

Appendix

Feedback on Value Statements- Safety – By Target vs. Non-Target

Value Statement	Target Segment	Number of Mentions by Rank Order 1-5 Target vs. Non-Target (n=40 Respondents Reporting)	Average Rank	Average Points
S-4 *"Tapentadol Extended Release offers a favorable tolerability profile that older patients…"*	Target	9 5 4 2	2.0	29
	Non-Target	8 5 3 2 2	2.3	27
S-1 *"86.2% of Tapentadol Extended Release…"*	Target	7 5 3 1 4	2.5	23
	Non-Target	6 5 4 3 2	2.5	22
S-5 *"Tapentadol Extended Release is associated with greater persistency and higher rates of…"*	Target	2 2 5 5 6	3.6	16
	Non-Target	3 4 2 2 9	3.5	17
S-2 *"Tapentadol Extended Release is not metabolized through the cytochrome…"*	Target	2 5 2 5 6	3.4	17
	Non-Target	1 2 6 8 3	3.5	15
S-3 *"The tamper-resistant formulation…"*	Target	3 6 7 4	3.6	16
	Non-Target	2 4 5 5 4	3.3	20



Q1: How would you prioritize the value proposition statements from most preferable to least preferable when considering moderate to severe chronic pain?
Q2: How would you distribute 100 points across these two statements? The more points you allocate to a statement, the more preferable it is to you. 98

Appendix

Feedback on Value Statements- Tolerability – By Pharmacy vs. Medical

Value Statement	Target Segment	Number of Mentions by Rank Order 1-2 Medical Director vs. Pharmacy Director (n=40 Respondents Reporting)	Average Rank	Average Points
T-1 *"In a 52-week safety study, patients receiving 1apentadol Extended Release experienced…"*	Medical Director	18 / 6	1.3	59
	Pharmacy Director	14 / 2	1.1	65
T-2 *"More Tapentadol Extended Release patients completed treatment and experienced…"*	Medical Director	6 / 18	1.8	41
	Pharmacy Director	2 / 14	1.9	35

■ Rank Order 1 ■ Rank Order 2

Q1: How would you prioritize the value proposition statements from most preferable to least preferable when considering moderate to severe chronic pain?
Q2: How would you distribute 100 points across these two statements? The more points you allocate to a statement, the more preferable it is to you. 99

Appendix

Feedback on Value Statements- Tolerability – By Target vs. Non-Target

Value Statement	Target Segment	Number of Mentions by Rank Order 1-2 Target vs. Non-Target (n=40 Respondents Reporting)	Average Rank	Average Points
T-1 *"In a 52-week safety study, patients receiving Tapentadol Extended Release experienced…"*	Target	15 / 5	1.3	59
	Non-Target	17 / 3	1.2	64
T-2 *"More Tapentadol Extended Release patients completed treatment and experienced…"*	Target	5 / 15	1.8	42
	Non-Target	3 / 17	1.9	37

Q1: How would you prioritize the value proposition statements from most preferable to least preferable when considering moderate to severe chronic pain?
Q2: How would you distribute 100 points across these two statements? The more points you allocate to a statement, the more preferable it is to you. 100

Appendix

Feedback on Value Statements- Dosing & Administration – By Pharmacy vs. Medical

Value Statement	Target Segment	Number of Mentions by Rank Order 1-3 Medical Director vs. Pharmacy Director (n=34 Respondents Reporting)	Average Rank	Average Points
DA-1 *"Tapentadol Extended Release is available in 5 doses strengths…"*	Medical Director	12 / 7 / 1	1.5	43
	Pharmacy Director	10 / 3 / 1	1.4	41
DA-3 *"Simple conversion calculations make it easy for providers to switch…"*	Medical Director	5 / 10 / 5	2	35
	Pharmacy Director	4 / 9 / 1	1.8	40
DA-2 *"Tapentadol Extended Release has been studied in multiple pain conditions in doses up to…"*	Medical Director	3 / 3 / 14	2.6	23
	Pharmacy Director	2 / 12	2.9	18

*Note: Statement DA-4 was a late addition to the research and was only tested in 6/40 respondents.
Q1: How would you prioritize the value proposition statements from most preferable to least preferable when considering moderate to severe chronic pain?
Q2: How would you distribute 100 points across these two statements? The more points you allocate to a statement, the more preferable it is to you. 101

Appendix

Feedback on Value Statements- Dosing & Administration – By Target vs. Non-Target

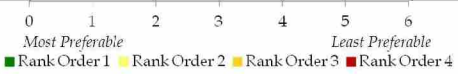
Value Statement	Target Segment	Number of Mentions by Rank Order 1-3 Target vs. Non-Target (n=34 Respondents Reporting)	Average Rank	Average Points
DA-1 *"Tapentadol Extended Release is available in 5 doses strengths…"*	Target	10 / 7 / 1	1.5	38
	Non-Target	12 / 3 / 1	1.3	47
DA-3 *"Simple conversion calculations make it easy for providers to switch…"*	Target	6 / 8 / 4	1.9	40
	Non-Target	3 / 11 / 2	1.9	33
DA-2 *"Tapentadol Extended Release has been studied in multiple pain conditions in doses up to…"*	Target	2 / 3 / 13	2.6	22
	Non-Target	1 / 2 / 13	2.8	20

*Note: Statement DA-4 was a late addition to the research and was only tested in 6/40 respondents.
Q1: How would you prioritize the value proposition statements from most preferable to least preferable when considering moderate to severe chronic pain?
Q2: How would you distribute 100 points across these two statements? The more points you allocate to a statement, the more preferable it is to you. 102

Appendix

Feedback on Value Statements- Dosing & Administration – By Pharmacy vs. Medical

Value Statement	Target Segment	Average Rank	Average Points
DA-3 *"Simple conversion calculations make it easy for providers to switch…"*	Medical Director	1.8	31
	Pharmacy Director	1.5	28
DA-1 *"Tapentadol Extended Release is available in 5 doses strengths…"*	Medical Director	2.3	24
	Pharmacy Director	2.5	33
DA-4* *"Based on clinical trials, dosing for oxycodone IR or CR can be converted…"*	Medical Director	2.5	31
	Pharmacy Director	2.5	23
DA-2 *"Tapentadol Extended Release has been studied in multiple pain conditions in doses up to…"*	Medical Director	3.5	18
	Pharmacy Director	3.5	18



*Note: Statement DA-4 was a late addition to the research and was only tested in 6/40 respondents.
Q1: How would you prioritize the value proposition statements from most preferable to least preferable when considering moderate to severe chronic pain?
Q2: How would you distribute 100 points across these two statements? The more points you allocate to a statement, the more preferable it is to you.

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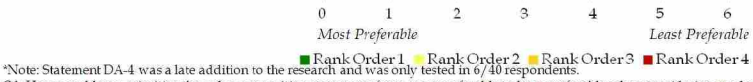
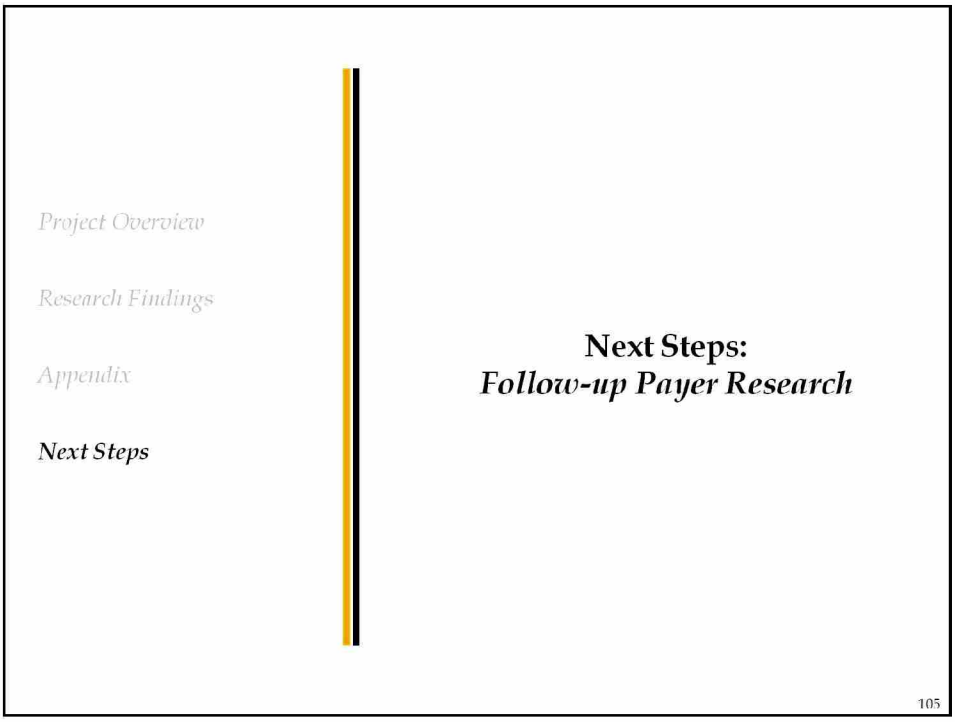
Appendix

Feedback on Value Statements- Dosing & Administration – By Target vs. Non-Target

Value Statement	Target Segment	Number of Mentions by Rank Order 1-4 Target vs. Non-Target (n=6 Respondents Reporting)	Average Rank	Average Points
DA-3 *"Simple conversion calculations make it easy for providers to switch…"*	Target	1 1	1.5	35
	Non-Target	2 1 1	1.8	28
DA-1 *"Tapentadol Extended Release is available in 5 doses strengths…"*	Target	2	3	20
	Non-Target	2 1 1	2	30
DA-4* *"Based on clinical trials, dosing for oxycodone IR or CR can be converted…"*	Target	1 1	1.5	40
	Non-Target	1 2 1	3	23
DA-2 *"Tapentadol Extended Release has been studied in multiple pain conditions in doses up to…"*	Target	2	4	13
	Non-Target	1 1 2	3.3	20



*Note: Statement DA-4 was a late addition to the research and was only tested in 6/40 respondents.
Q1: How would you prioritize the value proposition statements from most preferable to least preferable when considering moderate to severe chronic pain?
Q2: How would you distribute 100 points across these two statements? The more points you allocate to a statement, the more preferable it is to you. 104



Next Steps

Research Objectives

- **Primary objective:**
  Generate payer feedback and recommendations regarding the overall payer account manager deck for Nucynta ER. The research will be aimed towards gaining feedback on the deck and supporting clinical and value proposition messages, in order to ultimately determine the overall brand promise for Nucynta ER. This will allow OMJP to best position the product to payers, in the context of existing chronic pain products.

- **Key research questions:**
  - What structural feedback do payers have on the slide deck in terms of flow/order of content, content to be added/deleted and prioritization of information?
  - What is the underlying benefit/importance of Nucynta ER?
  - What does Nucynta ER offer in relation to other treatments in the chronic pain market? What specific needs/voids does the product fulfill?
  - How does the product add value to payer organizations? Why would this product be important to an organization?
  - What specific attributes should be highlighted to best position the product in the chronic pain space?
  - What does the story of Nucynta ER say/mean to payers?
  - How would payers recommend positioning the product to the payer audience?
  - What one key word would payers use to describe the overall value of Nucynta ER?

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Next Steps

Sample Design and Method

- **Sample Design:**
  PharmaStrat has provided a sample design option consistent with previous OMJP provided feedback and research objectives. As such, PharmaStrat will look to ensure adequate representation of the following respondents:
  - Book of Business (Commercial, Medicare)
  - Target Respondent Group (60% Medical Director vs. 40% Pharmacy Director)
  - MCO Region/Scope (National vs. Regional)

Target Segment	Target Respondent	Sample Size
Commercial MCOs	Medical Directors	12
	Pharmacy Directors	8
Medicare MCOs	Medical Directors	6
	Pharmacy Directors	4
Total		30

- **Method:**
  - 45 minute telephone-depth-interviews
  - WebEx assisted exposure to clinical deck
  - Voice-over recorded summary of each slide

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Next Steps

Timeline

PHASE	DELIVERABLE(S)	TASK	9/27 - 10/1	10/4 - 10/8	10/11 - 10/15	10/18 - 10/22	10/25 - 10/29
Project Initiation	Project Kick-off	Conduct team kick-off meeting					
Discussion Guide Development	Discussion Guide	OMJP submits draft slide deck stimuli to PSI					
		PSI develops discussion guide to address key research questions					
		PSI submits draft discussion guide to OMJP for review					
		OMJP reviews discussion guide, submits feedback					
		PSI finalizes discussion guide with revisions set forth by OMJP team					
Recruiting Respondents	Recruiting	Recruit respondents according to action plan					
Fielding	Kick-off TDIs	PSI conducts 3 kick-off TDIs					
	Team Debrief	PSI debriefs with OMJP in order to revise discussion guide as needed					
	Moderation of TDIs	Moderate telephone interviews					
Insight Analysis and Final Report Development	Final Report	PSI to prepare topline findings					
		PSI to submit topline/interim findings (if requested)					
		Prepare final report with key findings and recommendations					
		Deliver final report electronically					
		Final presentation (if requested)					TBD

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